Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

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A report submitted by GHK on behalf of EPEC
in association with Triveritas

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Contents

Executive summary ........................................................................................................... 1
1 Introduction .................................................................................................................. 7
  1.1 The study work programme and methodology ................................................... 7
  1.2 The structure of this report .................................................................................. 10
2 Problem Definition ...................................................................................................... 11
  2.1 There is insufficient availability of veterinary medicinal products ...................... 11
  2.2 There are deficiencies in the operation of the single market .............................. 22
  2.3 There is a high administrative burden imposed on industry ............................ 25
  2.4 Key messages .................................................................................................... 28
3 Policy Objectives and Policy Options ......................................................................... 30
  3.1 Policy objectives of the legislative revision ....................................................... 30
  3.2 Policy options for the legislative revision .......................................................... 32
  3.3 Key messages .................................................................................................... 45
4 The Impacts of the Policy Options ............................................................................. 46
  4.1 Approach to measuring options’ impacts ............................................................ 46
  4.2 Option appraisals ............................................................................................... 47
  4.3 Synthesis of the results of the impact assessment ............................................... 62
5 Conclusions and Recommendations .......................................................................... 71
  5.1 Developing ‘packages’ of policy options .............................................................. 71
  5.2 A synthesis package of policy options ................................................................ 76
  5.3 Other options not in the synthesis package have some potential to deliver positive
      change but would need further development to be viable .................................... 83
  5.4 Indicators for future monitoring and evaluation .................................................. 84
6 Concluding remarks ................................................................................................... 86
Annex 1 Method of approach to the study ................................................................... 89
Annex 2 Standard Cost Model Methodology ............................................................... 96
Annex 3 Overview of National Datasets on Authorised Products ................................. 99
Annex 4 Key to the ATCvet Classification System ..................................................... 100
Annex 5 Analysis of National MA Databases ............................................................. 101
Annex 6 Analysis of Marketing Authorisation Applications ....................................... 119
Annex 7 Detailed Standard Cost Model Results ......................................................... 140
Annex 8 The Veterinary Medicinal Products Industry ................................................ 142
Annex 9 Case studies of risks to human and animal health ........................................ 147
Annex 10 Case study of the usage of the cascade ....................................................... 156
Annex 11 Participants in the consultation exercise ..................................................... 160
Annex 12 Detailed Appraisal of Policy Options .......................................................... 163
Executive summary

An assessment of the impact of revisions to veterinary pharmaceutical legislation was commissioned by the European Commission (initially DG Enterprise and Industry then subsequently DG Health and Consumers) and carried out by the European Policy Evaluation Consortium (EPEC). One EPEC member – GHK Consulting1 – carried out the study, assisted by Triveritas. The study ran from November 2009 to June 2011.

The study documents problems associated with EU legislation on veterinary medicine and assesses the impacts of proposed options for legislative reform

This study contributes to the preparation of an impact assessment of proposed revisions to veterinary pharmaceutical legislation. Specifically, it was commissioned to provide:

- Data that substantiate the problems in the current operation of legislation; and,
- An assessment of the impacts of the policy options identified to address these problems.

There were five research stages:

- **Inception and scoping:** Stakeholders were contacted in order to establish the coverage and availability of the required datasets;
- **Problem definition:** The study team collected data to substantiate the problem facing the legislative framework for veterinary medicinal products. This problem definition consisted of:
  - The collection of national datasets of marketing authorisations2 (MAs) (19 countries provided data) in order to analyse the distribution of authorisations within the EU/EEA, disaggregated according to target species etc;
  - The collection of data on MA applications received by the competent authorities, including applications for new MAs and the renewal of existing MAs etc3;
  - A business survey (19 responses) to collect data on the costs of complying with the legislation, after which a Standard Cost Model was developed to measure administrative burdens;
  - The collection of data on the animal pharmaceutical industry, based on information contained within the national MA datasets and material provided by a trade association for the sector;
  - Case studies of selected issues which provided qualitative information where no quantitative data were available. This included case studies of the risks posed to human and animal health due to a lack of availability of medicines, and a case study of the operation of the ‘cascade’4.
- **Options development:** On the basis of the problem definition the study team worked with DG Health and Consumers to finalise a list of 49 policy options for inclusion in the impact assessment;
- **Consultation and options appraisal:** The impacts of all 49 policy options were assessed through a consultation exercise involving representatives from regulatory bodies, businesses and trade associations, and end user groups (e.g. veterinarian associations). In-depth research was undertaken in six countries (Cyprus, Finland, Germany, Poland, Romania, and the United Kingdom);
- **Reporting:** a final report was prepared and reviewed with the study steering committee.

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1 www.ghkint.com
2 To be marketed within the EU/EEA all veterinary medicinal products must first receive a Marketing Authorisation
3 Once granted MAs must periodically be renewed. Any change to a MA – from an administrative amendment to the extension of a MA to a new species – requires an ‘application’ to the competent authority or authorities
4 The cascade allows veterinarians to use medicines ‘off label’ (i.e. outside of the conditions of their MA) in exceptional circumstances (e.g. where there are no authorised medicines available)
There are problems with the current operation of the legislation

Problems were identified in three broad areas: the availability of medicines; the operation of the single market; and the administrative burdens imposed on companies. These are reviewed below.

The results are regarded as robust, though the evidence base could be stronger. Collecting data on the existing situation was challenging. There is, for example, no centralised dataset on marketing authorisations so this information has to be gathered from each Member State. Some Member States were unable to provide data in a usable format. Data coding protocols vary between national competent authorities, meaning that it is often not possible to compare datasets from different countries. Other datasets – for instance showing pricing information – were not publicly available.

There is significant variation in the availability of veterinary medicinal products – by Member State, species and therapeutic category

The study has identified a number of problems with the availability of veterinary medicinal products. Case studies of avian influenza and bluetongue demonstrate that a lack of suitable available medicines can have serious consequences for the protection of human and animal health. Without authorised medicines, veterinarians have to resort to using products ‘off-label’ through the cascade.

Smaller countries tend to have fewer authorised products

There is a strong relationship between the size of the market (as measured indirectly by reference to population of farmed livestock species) and the number of MAs. The countries with the smallest animal populations, such as Malta and Cyprus, also had the fewest authorised medicines (just 311 MAs in Malta, compared to 2,944 MAs in France).

There are very few authorised products for some minor species

More products are authorised for use with dogs than any other species. The ‘top four’ species in terms of the number of authorisations (dogs, cattle, pigs and cats) on average accounted for 70 per cent of all species authorisations within a national market. Conversely, there are typically very few products authorised for use with ‘minor’ species, particularly bees and certain species of fish. In some countries there are no authorised bee medicines.

There are very few authorised products for some therapeutic categories

Whilst MA databases do not contain information on the conditions that medicines are authorised to treat, they do provide information on the therapeutic categories of the products. Antiparasitics, antiinfectives and immunologicals on average accounted for 63 per cent of all authorisations within a national market. Particularly in small markets there were comparatively few MAs within many therapeutic categories.

Innovation in the sector is tending to reinforce these patterns

The number of applications for new MAs submitted each year is low, and few of these applications concern products aimed at minor species. A lack of data on products submitted to national competent authorities prevented a comprehensive analysis of the number of applications submitted each year, but data on applications submitted through the ‘European’ procedures suggests that applications primarily involve the major species (just 4 applications for products targeting bees were submitted between 1997 and 2009).

Actual levels of product availability are lower in smaller markets than authorisation data suggest

Commercial decisions regarding return on investment drive actual product availability, even where a MA holder has spent resources obtaining an authorisation. There are no data on product availability, and so a selection of leading businesses were asked to indicate which of their products were available within five exemplar countries. In Romania and Cyprus – both relatively small markets – around 60

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5 For this study the following minor species were considered: horses, goats, turkeys, bees, and fish species (with the exception of salmon)

6 There are four routes to a MA, of which three are ‘European’ – the Centralised Procedure, the Mutual Recognition Procedure (MRP) and the Decentralised Procedure (DCP) – in that they involve more than one national competent authority
per cent of authorised products were actually available. In these same countries the proportion was as low as around 40 per cent of MAs for Centralised Procedure authorisations.

There are deficiencies in the operation of the single market

There is evidence of deficiencies in the operation of the single market in veterinary medicinal products, though data accessibility problems mean that many measures of the operation of the single market could not be obtained. Efforts made to investigate the extent to the variation in price of selected products across the single market were unsuccessful. However, analysis of data on the identity of MA holders suggests that the majority of companies (62 per cent of the total) only held MAs in a single national market. Just 4 per cent of companies held an MA in all 18 of the national markets for which data were available (this would, for instance, be the case for any company that had a product authorised through the Centralised Procedure). These data suggest that most businesses only operate within a single national market.

Whilst there are methodological problems in making the calculation, data on MAs also indicate that the majority of product brands (67 per cent of the total) were only authorised in a single national market. Just 1 per cent of product brands were authorised in all 19 national markets for which data were available.

The legislation imposes a high administrative burden on the industry

The regulatory requirements of the legislation – e.g. the conditions that businesses must meet in order to have a product authorised – impose administrative burdens on industry. The magnitude of these burdens was measured by the study team through the development of a standard cost model (prepared according to European Commission guidelines) and a survey of businesses.

The total annual administrative burden imposed on businesses by the legislation was estimated to be EUR 538 million per year. Total sector sales in 2008 were estimated to be EUR 4.3 billion, meaning that the administrative burden is equal to around 13 per cent of the turnover of the veterinary medicinal products sector. The administrative burden breaks down as follows:

- The cost of applying for new MAs was estimated to amount to EUR 91 million per year;
- Packaging and labelling was the single largest cost, equal to EUR 184 million per year;
- The remainder (EUR 262 million per year) constituted the costs associated with an existing MA, of which the administrative burden incurred through MA variations was the single largest component (an estimated EUR 134 million per year).

The objectives for the legislative revision are to address these high level problems

The general objectives of the legislative revision relate directly to the three high level problem areas, i.e.:

- To improve the functioning of the single market;
- To enhance the level of protection of human and animal health, e.g. through increasing the availability of veterinary medicinal products); and,
- To reduce the administrative burden imposed on businesses;

Nested within these general objectives are five specific objectives which address aspects and causes of the high level problems:

- To simplify procedures for obtaining a new MA for a veterinary medicinal product: Revisions to procedures through which products obtain a MA, and proposals for harmonising existing MAs;

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7 The fact that end consumers’ access to products is often mediated via veterinarians, whose pricing strategies vary widely, makes product pricing more opaque than in ‘standard’ consumer markets

8 E.g. products might be known by different brands in different countries

9 The term ‘brand’ is used to signify an individual product name, as opposed to a MA (e.g. the brand ‘Advantage’)
To simplify legislative requirements for products once they have obtained a MAs: Revisions to requirements in respect of pharmacovigilance, MA renewals, MA variations, data reporting, and packaging and labelling;

To provide incentives for the development of new veterinary medicinal products: Whether data protection arrangements can be used to incentivise the development of new products;

To ensure that the legislation is able to meet emerging needs and challenges: The scope of the legislation with regard to new technologies and the approach towards antimicrobial resistance;

To ensure the effective operation of the legislation: Harmonisation and oversight of in-market control systems, and improved monitoring data.

Packages built from the proposed policy options have the potential to significantly reduce administrative burdens, improve product availability and the functioning of the single market, whilst maintaining high standards of health protection.

DG Health and Consumers identified 49 policy options for inclusion in the impact assessment. Each of these policy options was assessed against four impact criteria, corresponding to the general objectives for the legislative reform:

- The protection of human and animal health;
- The availability of medicines;
- The functioning of the single market; and,
- Administrative burdens.

The impact assessment process drew on material collected as part of the consultation exercise, which included a wide range of stakeholder types. Where possible the impact on administrative burdens was quantified through use of the standard cost model.

Policy options need to be combined into coherent ‘packages’ to achieve reform of the system as a whole; the preferred composition of the package varies according to the relative priority given to the different strategic objectives.

The policy options included in the impact assessment each address a specific aspect of the problem and a particular part of the regulatory ‘system’. They therefore need to be combined into a coherent ‘package’ of measures to provide a complete response to the reform challenge.

A given policy option does not necessarily perform equally well against all four assessment criteria. For instance, a policy option might reduce administrative burdens whilst simultaneously reducing the level of protection of human and animal health (e.g. if the amount of data that must be submitted as part of a MA application is reduced). Consequently, the ‘preferred’ packages of options is influenced by the relative importance or ‘weighting’ given to each of the policy objectives.

To illustrate this, three potential packages were developed, each prioritising a different objective:

- A reduction in administrative burdens for industry: Prioritising reductions in administration burdens would put a focus on simplification of MA requirements and could deliver savings worth an estimated EUR 210 million per year;

- An increase in the availability of medicines: Prioritising improvements in the availability of medicines would mean inclusion of measures that allow authorised medicines to be used throughout the EU/EEA and on enhanced data protection and rewards for new product development. These measures would also reduce administrative burdens by an estimated EUR 82 million per year;

- An improvement in the free movement of goods: Prioritising the single market would mean focusing on options that harmonise national requirements and remove barriers to the movement of goods, but would again see less of an impact on administrative burdens (with cuts worth an estimated EUR 82 million per year, or an increase in the burden worth EUR 89 million per year, depending on the choice of options).
A ‘synthesis’ package of options has been identified that simultaneously aims to protect health, increase medicine availability, cut administrative burdens and improve the integrity of the single market.

A ‘synthesis’ package of options has been identified which aims for a balanced approach to the reform objectives and which would be expected to deliver improvements on availability, free movement of goods, and administrative burdens – without undermining human or animal health. This package would generate savings in the administrative burden worth EUR 194 million per year (a reduction of around a third from the current level of burdens).

Consultation with a wide range of stakeholders suggests that there is considerable support for the measures proposed in this synthesis package, though there are also issues regarding the details of implementation that will need to be addressed before a consensus as to the way forward can be reached (see Figure ES.1).

Figure ES.1: A synthesis package of policy options

- **Requirements for new MAs**
  - Option 2.1: One MA is valid throughout the EU/EEA; an EU body oversees
  - Option 5.1: Data requirements are reduced
  - Option 5.2: Products may be authorised without full dossiers
  - Option 7.1: MAs with a record of safe use are allowed to freely circulate
  - Option 7.2: SPCs are systematically harmonised

- **Requirements for existing MAs**
  - Option 8.2: Simplify pharmacovigilance requirements
  - Option 9.2: Restrict renewals to products based on their risk-profile
  - Option 10.1: Reduce data recording and reporting
  - Option 11.1: Abolition of prior approval of packaging/ labelling
  - Option 11.2: Reduction the the amount of text on packaging/ labelling
  - Option 11.3: Non-official languages are permitted
  - Option 12.1: Variations requirements are simplified

- **Data protection**
  - Option 14.5: Decouple rewards for new developments from the initial MA
  - Option 14.6: Data protection of environmental risks changed to match safety/ efficacy data
  - Option 14.8: Extend to 20 years the data protection period for fish, bees and other specific species/ indications

- **New treatments**
  - Option 16.1: The scope of the legislation with regard to new treatments is clarified

- **Control and monitoring**
  - Option 18.1: National control systems must meet EU standards
  - Option 18.2: Harmonised EU sanctions are introduced
  - Option 19.1: Enforcing a European database of MAs

Clearer specification of some of the options will be needed to engender support for them in negotiation and to facilitate their subsequent implementation.

Whilst in many cases there was broad agreement amongst stakeholders on the need for certain policy options, there was also a lack of a consensus about how they should be implemented. As part of the consultation exercise, stakeholders were asked to identify any implementation problems and to propose potential solutions. Consultees suggested a number of potential revisions that could be introduced in order to engender wider support.
A peer-review system for MA assessments: There was support for the introduction of a system through which a single MA is valid throughout the EU/EEA (Option 2), provided it was backed by an accreditation system enforced by an EU body which would ensure quality standards were met. In addition, it was suggested that a peer-review system for individual MA assessments would be needed, for instance whereby two competent authorities would be responsible for each MA;

Eligibility restrictions based on when MAs were awarded: There was widespread concern about the thoroughness of historical MA assessments and the quality of national pharmacovigilance systems. Consequently, if products with an existing MA were to be allowed to freely circulate within the EU/EEA there would be merit in restricting eligibility to products authorised during the timeframe of EU veterinary pharmaceutical legislation (either 2001/2004, or perhaps 1981);

Eligibility restrictions based on the risk profile of products: Concerns over the quality of scientific assessments and the dangers of relaxing some requirements (e.g. in respect of pharmacovigilance) could be assuaged by restricting some options to lower-risk products. A system for defining ‘lower-risk’ would need to be created.

Monitoring indicators should be collected in order to assess the effectiveness and impact of the legislative revision, and the legislation should be evaluated

In order to assess whether the legislative revision is achieving its objectives, and whether there are any unexpected impacts, the European Commission will need to collect, review and publish monitoring indicators. It will also be necessary to undertake a more detailed evaluation exercise once sufficient time has elapsed, in order to thoroughly review the performance of the revised legislation.

Monitoring indicators should align with the general objectives established for the legislative revision:

To increase the availability of medicines: data on MA applications received by the authorities should be collected in order to analyse trends in new product development (e.g. minor species); data on the number of MAs should be analysed in order to measure overall trends in availability (disaggregated by species and geography in order to measure availability within under-served markets); and, data on the extent to which products are marketed could be collected by the authorities in order to analyse trends in actual product availability;

To improve the functioning of the single market: data on MA holders should be analysed in order to ascertain the extent to which MA holders are present on more than one national market;

To reduce the administrative burden on businesses: A periodic electronic survey of companies should be undertaken in order to quantify the administrative burden through a SCM.

The collection of monitoring indicators would be significantly easier and more cost-effective if the policy option concerning the completion of a EU database of MAs (Option 19) was successfully implemented.
1 Introduction

In November 2009, the European Policy Evaluation Consortium (EPEC) was commissioned by the European Commission (initially DG Enterprise and Industry then subsequently DG Health and Consumers) to undertake an assessment of the impacts of the revision of veterinary pharmaceutical legislation. The study has been led by one member of EPEC – GHK Consulting (GHK) – assisted by Triveritas.

This is a Final Report of the study findings, and follows on from a Draft Final Report\textsuperscript{10} that was submitted in May 2011, and discussed at a Steering Committee meeting that was held on 26 May 2011. Previous reports included a First Activity Report that was submitted in March 2010\textsuperscript{11}, and a Second Activity Report that was submitted in October 2010\textsuperscript{12}.

1.1 The study work programme and methodology

The work programme and methodology for the study were initially set out in the proposal that was submitted by GHK in September 2009\textsuperscript{13}, in response to the Terms of Reference issued by DG Enterprise and Industry. Figure 1.1 provides an overview of the work programme. Detailed descriptions of the key stages of the study are set out below.

Figure 1.1 Overview of the study work programme

Stage 1: Inception and scoping

\textit{Purpose}: To identify key issues and scope out the data collection phase of the study

Stage 2: Problem definition

\textit{Purpose}: To collect data on the problems that need to be addressed through the legislative revision

Stage 3: Options development

\textit{Purpose}: To define policy objectives and policy options for the legislative revision

Stage 4: Consultation and options appraisal

\textit{Purpose}: To collect the evidence used to measure impacts and appraise the policy options

Stage 5: Reporting

\textit{Purpose}: To bring together the results of the study and report to the European Commission

1.1.2 Stage 1: Inception and scoping

The inception and scoping stage ran from December 2009 through till March 2010. The purpose of this stage of the study was to collect qualitative material on the nature of the problem facing the legislative framework for veterinary medicinal products, and to scope out the data collection phase of the study. Upon completion of this stage of the study a First

\textsuperscript{10} EPEC (May 2011) Assessment of the impact of the revision of veterinary pharmaceutical legislation: Draft Final Report
\textsuperscript{11} EPEC (March 2010) Assessment of the impact of the revision of veterinary pharmaceutical legislation: First Activity Report
\textsuperscript{12} EPEC (October 2010a) Assessment of the impact of the revision of veterinary pharmaceutical legislation: Second Activity Report
\textsuperscript{13} GHK (September 2009) Assessment of the impact of the revision of veterinary pharmaceutical legislation: Proposal
Activity Report\textsuperscript{14} was submitted to the European Commission that outlined the data that would be collected as part of the problem definition, and refined the initial list that was contained with the Terms of Reference for the study.

1.1.3 Stage 2: The problem definition

The collection of evidence for the problem definition took place between March 2010 and October 2010, based on the scoping exercise carried out as part of Stage 1 of the study. Drawing on the results of this data gathering exercise, a Second Activity Report was submitted to the European Commission in October 2010\textsuperscript{15}. This report presented an analysis of the data that were collected, including an initial assessment of the problem definition. The Second Activity Report was accompanied by a technical report which presented raw data\textsuperscript{16}.

Section 2 of this report provides an overview of the results of the problem definition. Supporting data analysis is provided in the Annexes to this report (see below for details).

In summary, the following information has been collected in order to provide the evidence needed for the problem definition (a more detailed description of the methodology employed and a commentary on how this exercise fits with the Terms of Reference for the study, is included in Annex 1):

- **Data on Marketing Authorisations (MAs):** National competent authorities hold data on all products authorised for their markets. Since there is no centralised database of this information, GHK had to contact all 30 EU/EEA competent authorities requesting their national datasets (as at May 2010). A total of 19 countries provided this information in a usable format. To varying degrees these databases contained information relating to the scope of the authorisation (e.g. the target species etc). Further information on the coverage of the MA databases is provided in Annex 2, and detailed analysis of MA databases is attached as Annex 5;

- **Data on MA applications:** The European Medicines Agency (EMA) provided data on MA applications received through the Centralised Procedure and the Heads of Medicines Agency (HMA) provided data on MA applications received through the Decentralised Procedure (DCP) and Mutual Recognition Procedure (MRP). Only the United Kingdom provided data on applications received by national competent authorities through the National Procedure. Again, to varying degrees these databases contained information relating to the nature of the product (e.g. the target species etc). Analysis of the applications data is attached as Annex 6;

- **Data on the costs to industry of complying with the legislation:** The development of a Standard Cost Model (SCM) for the legislative framework for veterinary medicinal products was a key part of the study, both in order to ascertain whether the magnitude of the administrative burden is a problem, and to measure the impacts of the policy options (Section 1.1.5). A survey of businesses was carried out in order to collect data on the time taken and costs associated with complying with each requirement of the legislation. A total of 19 companies responded to the survey. Extrapolating this information it was possible to develop an EU-wide SCM for the legislation (see Annex 2 for further details on the methodology employed, and Annex 7 for details of the results of the SCM);

- **Animal pharmaceutical industry data:** Databases on MAs included information on the identity of the MA holder, which was analysed in order to provide evidence as to the structure of the industry. Further data on the animal pharmaceutical industry was

\textsuperscript{14} EPEC (March 2010) Assessment of the impact of the revision of veterinary pharmaceutical legislation: First Activity Report

\textsuperscript{15} EPEC (October 2010a) Assessment of the impact of the revision of veterinary pharmaceutical legislation: Second Activity Report

\textsuperscript{16} EPEC (October 2010b) Assessment of the impact of the revision of veterinary pharmaceutical legislation: Second Activity Report: Technical Report
collected from material published by a trade association for the sector, IFAH-Europe. Analysis of the animal pharmaceutical industry is attached as Annex 8.

- **Case studies of the risks posed to animal and human health:** In order to provide examples of the relationship between the availability of medicines and the protection of human and animal health, case studies were undertaken of bluetongue and avian influenza. These case studies drew on the results of a literature review and discussions with experts from industry and regulatory bodies. The case studies are attached as Annex 9;

- **A case study of the usage of the cascade:** Discussions with competent authorities and national veterinary associations indicated that no data on the usage of the cascade are systematically collated, meaning that it was not possible to measure the usage of the cascade (see Annex 1 for more details). In the absence of data, a case study was undertaken of the usage of antibiotic footbaths through the cascade in the United Kingdom (attached as Annex 10).

### 1.1.4 Stage 3: Options development

The development of options for inclusion in the impact assessment commenced following the submission of the Second Activity Report in October 2010. An initial list of policy options was developed by the European Commission, and EPEC commented on the phrasing of each option. A final list of policy options was provided by the European Commission in February 2011. The policy options are described in Section 3.

### 1.1.5 Stage 4: Consultation and options appraisal

The consultation and options appraisal stage of the study ran from February 2011 to April 2011. The purpose of this work was to collect quantitative and qualitative data on the impacts of each of the policy options, and to review issues and challenges with the implementation of the proposals.

The consultation exercise consisted of a number of different strands, as follows:

- **Consultation with stakeholders in 6 countries:** face-to-face and telephone interviews were undertaken with stakeholders in 6 exemplar countries, chosen in order to achieve a balance between small and large markets, and new and old Member States. The 6 countries were: Cyprus, Finland, Germany, Poland, Romania, and the United Kingdom. In each country efforts were made to arrange face-to-face or telephone meetings with representatives from: the national competent authority, the principle industry trade association, and the principle veterinarian organisation. In some cases stakeholders instead responded to the consultation by submitting the policy option ‘survey’ (see below), whilst in other countries it was not possible to identify a relevant consultee (e.g. in Cyprus there is no industry body representing medicine manufacturers). A total of 13 organisations were consulted through these research methods;

- **Consultation with other key stakeholders:** Face-to-face and telephone interviews were held with a total of 3 organisations representing the key stakeholder groups in the veterinary medicines sector. This included individuals from: the Federation of Veterinarians of Europe (FVE); Copa-Cogeca representing farmers; and the EMA;

- **An industry workshop:** The purpose of the industry workshop was to review each of the policy options and to discuss and validate the methodology used to measure administrative burdens through the SCM. The workshop was held in Brussels on 3 March 2011 and was attended by 15 industry representatives, including individuals from IFAH-Europe, the European Group for Generic Veterinary Products (EGGVP), and individuals from 12 animal health businesses, including a mixture of large and small companies, and manufacturers of novel and generics products;

- **A policy option ‘survey’ of stakeholders:** A ‘survey’ was prepared which listed all of the policy options. Survey respondents were asked to score the impact of each policy option, and also to review the workability of the proposals and identify any problems or
issues. The survey was given to each consultee within the 6 exemplar countries (see above), and was also sent to every national competent authority in the EU/EEA. IFAH-Europe and the FVE were also asked to circulate the survey amongst their national member organisations, representing industry and veterinarian bodies. A total of 31 survey responses were received.\(^{17}\)

Drawing on the information collected through the consultation exercise, the study team carried out an appraisal of the impacts of each of the policy options. Section 4 sets out an option-by-option summary of the results of the impact assessment, with supporting material provided in Annex 12. Table 4.23 provides a synthesis table that compares the impacts of each of the policy options. Section 5 presents various ‘packages’ of policy options, and provides a commentary on the selection of a synthesis package of options.

### 1.1.6 Stage 5: Reporting

This final stage commenced in April 2011 with the preparation of a Draft Final Report of the study findings that was submitted in May 2011. The submission of the Draft Final Report was followed by a Steering Committee meeting to discuss the results. Comments received were incorporated into this Final Report, which was submitted in June 2011.

### 1.2 The structure of this report

The remainder of this report is structured as follows:

- Section 2 presents the results of the problem definition;
- Section 3 presents the policy objectives for the legislative revision and sets out details of each of the policy options;
- Section 4 presents the results of the assessment of the impacts of the policy options;
- Section 5 provides the conclusions and recommendations of the study team;
- Section 6 contains concluding remarks.

Supporting material is provided in the Annexes to this report:

- Annex 1 provides a detailed description of the method of approach;
- Annex 2 contains a description of the methodology for the development of the SCM;
- Annex 3 summarises the contents of the national MA databases;
- Annex 4 contains an overview of the ATCvet classification system, which should be used in conjunction with the MA databases;
- Annex 5 presents a detailed analysis of national MA databases;
- Annex 6 presents a detailed analysis of MA application data;
- Annex 7 presents the results of the SCM;
- Annex 8 provides an overview of the veterinary medicinal products industry;
- Annex 9 presents case studies of the risks to human (avian influenza) and animal (bluetongue) health posed by a lack of availability of medicines;
- Annex 10 presents a case study of the usage of the cascade;
- Annex 11 lists the participants in the consultation exercise; and,
- Annex 12 presents a detailed appraisal of the impacts of the policy options.

\(^{17}\) Disaggregated as follows: 12 responses from industry representatives bodies and individual companies; 14 responses from national regulatory bodies and the EMA; and 5 responses from end user groups (national veterinarian organisations, the FVE and Copa-Cogeca)
2 Problem Definition

This section of the report analyses the problems with the design and operation of the legislative framework for veterinary medicinal products. The objectives and policy options for the legislative revision (see Section 3) have been formulated in order to address the problems identified.

The method of approach for the problem definition was introduced in Section 1.1.3. To recap, between March 2010 and October 2010 the study team collected a range of datasets covering various aspects of the operation of the legislative framework for veterinary medicinal products. In October 2010 a report was submitted to the European Commission which contained a detailed analysis of the datasets, and provided an initial overview of the problem definition. Three key problems were identified:

- There is insufficient availability of veterinary medicinal products;
- There are deficiencies in the operation of the single market;
- There is a high administrative burden imposed on industry.

Further analysis of each of these problems is presented below. Supporting material has been included within the Annexes to this report.

2.1 There is insufficient availability of veterinary medicinal products

Issues relating to the availability of veterinary medicinal products include:

- Smaller countries tend to have fewer authorised products;
- There are very few authorised products for some minor species;
- There are very few authorised products for some therapeutic categories;
- The number of applications for new authorisations submitted each year is low, and few applications concern products aimed at minor species;
- High proportions of authorised products are not marketed in smaller countries; and,
- Availability problems mean that medicines sometimes have to be used ‘off-label’.

Problems with the availability of veterinary medicinal products can have serious impacts on the protection of human and animal health, as illustrated by the following case studies on avian influenza and bluetongue. Extended versions of these case studies, complete with references, are attached as Annex 9.

Case Study 1 The impact on human health of avian influenza

Avian influenza is a highly contagious viral disease that affects many bird species and some mammals, and in rare cases has also affected humans. More significantly, avian influenza has the potential to recombine with human influenza, and in this case could result in a global disease pandemic. Avian influenza is present worldwide. A serious outbreak occurred in the Netherlands in 2003 and spread to Germany and Belgium, whilst other major outbreaks took place in South East Asia in 2004 and again in 2006.

Within animals, avian influenza spreads through contact with infected animals’ secretions, and wild waterfowl are thought to be able to transmit the disease to domesticated poultry and other birds. Low pathogenic viruses may cause no obvious symptoms in affected birds, but high pathogenic viruses can cause respiratory problems, swollen heads, appetite loss, diarrhoea and reduced egg production. Mortality rates can approach 100 per cent; the 2003 avian influenza outbreak in Europe

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18 EPEC (October 2010a) Assessment of the impact of the revision of veterinary pharmaceutical legislation: Second Activity Report
19 Annexes provide an update of the data presented in the October 2010 Second Activity Report.
necessitated the slaughter of more than 23 million poultry. In humans, avian influenza can cause severe respiratory diseases and has been fatal in approximately half of all laboratory-confirmed cases to date.

Hence avian influenza presents a serious threat to human and animal health. Especially since avian influenza is known to recombine with the human influenza virus, there is scope for a new virus to emerge and spread quickly between people. Globally, by 2008 more than 300 human avian influenza cases and approximately 90 human deaths had been recorded. Most cases of human avian influenza are thought to have been caused by direct contact with infected birds, though there have been a limited number of cases of human to human transmission.

Inactivated virus vaccines for avian influenza have been available for decades, whilst live recombinant vaccines are becoming available. The vaccines that are currently available do not prevent avian influenza infections, though they do reduce the clinical severity of the disease and the level of transmission between birds. There are disadvantages with current vaccines, however, which are relatively expensive, take time to result in immunity, and can have serious side-effects (e.g. depressed egg production in laying hens due to handling). Each vaccine only protects against specific avian influenza strains, and vaccine development is complicated by the constant evolution of influenza viruses. Due to the current very limited use of vaccination by Member States, producers of veterinary medicinal products do not actively produce, stock and market these and hence they are not readily available. In case of a rapid and large scale epidemic which would trigger a need for vaccination, it might be difficult to make available the required quantities in a relatively short time period.

### Case Study 2 The impact on animal health of bluetongue

Bluetongue is an insect-borne viral disease that affects ruminants and camelids, including cattle, sheep, goats and deer. The bluetongue virus is transmitted by biting midges and is one of the most widespread animal pathogens in the world, found in a latitudinal band stretching from 40°S to 53°N. Bluetongue is considered to be an enzootic disease in Europe, though climate change and globalisation have been identified as factors that have extended its range to include Northern Europe.

Bluetongue is listed as a disease by the World Organisation for Animal Health due to its potential to spread rapidly and the extent of its impact on animal health. The disease is characterised by inflammation and haemorrhages to the mucous linings of the mouth, nose and coronary band of the foot, though symptoms may also include fever, lameness and muscle degeneration. The mortality rate is particularly high in susceptible sheep flocks and under certain circumstances can reach 80 per cent. It has been estimated that between 1998 and 2006 bluetongue outbreaks in Europe resulted in the deaths of more than 1.5 million sheep. The lack of a cure for the disease means that outbreaks may necessitate the humane destruction of large numbers of animals. Surviving animals can be affected by reduced productivity and infertility.

Whilst bluetongue is well understood (the disease was first described in the 19th century), there are no known cures. Where an outbreak occurs, surveillance and protection zones are established which involve restrictions to the movement of animals and may include slaughter and vaccination where appropriate.

Preventative vaccines are available, though development costs are relatively high. Modified live virus vaccines are currently available for bluetongue, though there can be associated side-effects, including abortions and reduced milk production. Inactivated vaccines have recently been developed, though production costs are typically high. Gene-based vaccines for bluetongue are still at a developmental phase. The previous lack of safe inactivated vaccines necessitated serious restrictions for movements of vaccinated animal across the EU resulting in significant economic damage to all involved. Only their availability enabled EU policy makers to propose changes for a more flexible regulatory framework for this disease, which can be anticipated to alleviate much of the burden on stakeholders.

### 2.1.1 Smaller countries tend to have fewer authorised products

Analysis of data on the total number of authorised products in the EU/EEA showed significant variations between countries. The total number of authorised products within the 19 countries that provided data is shown in Figure 2.2. Figure 2.2 also shows the total
number of authorised product ‘brands’ within each national market\textsuperscript{20}. The analysis of data on product brands is necessary since there are differences in the way in which countries record MAs. For example, the same product may be recorded as a single MA in one country, but as multiple MAs in another (e.g. differentiated by dosage)\textsuperscript{21}. The impact of these differences is to inflate the total number of apparent MAs in countries where multiple sub-divisions are the norm.

Figure 2.2  There was considerable variation between countries in terms of the number of authorised products – from 296 products in Iceland to 2,944 products in France. Comparison between the number of authorised products and the number of authorised ‘brands’ highlights the differences in the way in which countries record MAs (e.g. Belgium and Norway).

The number of authorised products and authorised ‘brands’ on national markets, as at May 2010

Source: GHK analysis of MA databases

As is apparent from the data shown in Figure 2.2, smaller countries tend to have fewer authorised veterinary medicinal products. Figure 2.3 plots the number of authorised medicines against the animal population in the countries for which data were available (selected livestock species only). Note that medicines could be authorised for use with more than one species, meaning that the total number of medicines exceeds that shown in Figure 2.2.

\textsuperscript{20}‘Brand’ here is used to signify an individual product name. For example, in the UK there are 8 distinct authorisations for the product ‘Advantage’, differentiated by the species (cats or dogs), the animal size (small or large), and the dosage. For the purposes of analysis of product brands, these 8 authorisations are reduced to a single record for the brand ‘Advantage’.

\textsuperscript{21}The impact of these differences in national recording protocols on product authorisation data is significant. For example, in Finland the product ‘Advocate’ is recorded as 2 authorisations (differentiated by species), whereas in Belgium the same product is recorded as 30 authorisations (differentiated by species, animal size, dosage etc).
Figure 2.3 Smaller countries tend to have fewer authorised products

1000 Livestock Units (LSU\textsuperscript{22}) of cattle, pigs, sheep, horses, goats and poultry (2007) and the total number of MAs authorised for use with cattle, pigs, sheep, horses, goats, chickens and turkeys, as at May 2010

Source: GHK analysis of MA databases; Eurostat (ef_ov_lsft)\textsuperscript{23}

\textsuperscript{22} Livestock Units (LSU) are a reference unit which aggregate livestock from various species and age through the use of coefficients established on the basis of the nutritional or feed requirement of each type of animal. For Eurostat data the reference unit used is the grazing equivalent of one adult dairy cow producing 3,000 kg of milk annually (see http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Glossary:LSU)

\textsuperscript{23} http://epp.eurostat.ec.europa.eu/portal/page/portal/agriculture/data/database
2.1.2 There are very few authorised products for some minor species

The analysis of MAs for eleven ‘case study’ species\textsuperscript{24} demonstrated that there are considerable variations in the number of products authorised for use with each of the species. Figure 2.4 presents data on the number of products authorised for use with each of the 11 case study species, for the 15 countries that provided the necessary data.

Figure 2.4: More products are authorised for use with dogs than any other species. The ‘top 4’ species in terms of the number of authorisations (dogs, cattle, pigs and cats) on average accounted for 70 per cent of all species authorisations.

\textit{The number of products authorised for use with selected species, as at May 2010. Note that products can have multiple target species, meaning that the total number of authorised products exceeds that shown in Figure 2.2.}

![Bar chart showing the number of product authorisations for different species and countries.](chart)

Source: GHK analysis of MA databases

As Figure 2.4 suggests, there are comparatively few products authorised for use with certain ‘minor’ species. There is presently no EU definition of a minor species, though a paper produced by the EMA has defined ‘major species’ as cattle, sheep (for meat), pigs, chickens, salmon, dogs and cats\textsuperscript{25}. These were identified on the basis of EU-wide animal population data and consumption figures. By extension, all remaining animals were defined as minor species. For the case study species, the following would be considered minor species:

\begin{itemize}
  \item Horses;
  \item Goats;
  \item Turkeys;
  \item Bees; and,
  \item Other fish species, though most national databases do not distinguish among fish species, with the occasional exception of trout.
\end{itemize}

Figure 2.5 presents data on the number of products authorised for use with each of these minor species in the 13 countries that provided data.

\textsuperscript{24} Consisting of the two types of companion animal (dogs and cats) together with the principal food-producing species, as well as bees and fish species. All other animals were grouped together into an ‘other category’ (e.g. rabbits, ducks, geese and other companion animals). See Annex 1 for further details.

\textsuperscript{25} EMA (2009) EMEA Guidance for companies requesting classification as MUMS/ limited markets
Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

Figure 2.5 In comparison to other minor species, there are comparatively large numbers of products authorised for use with horses in most countries, and in certain countries (e.g. France and Romania) there are relatively large numbers of products authorised for use with goats. In contrast, there are very few products authorised for use with bees in any country, and in some (e.g. Finland and Malta) there are no products authorised for use with bees.

*The number of products authorised for use with selected minor species, as at May 2010*

Source: GHK analysis of MA databases

There are very few authorised products for some therapeutic categories

Using the Anatomical Therapeutic Chemical (ATC) (vet) classification system, it is possible to examine the therapeutic categories of veterinary medicinal products authorised in Europe. The ATCvet classification system categorises products according to their therapeutic use, starting with 15 categories labelled QA to QV. A key to the first tier of the ATCvet classification system is provided in Annex 4. Subsequent tiers provide greater therapeutic detail, but for the purposes of this report only the first tier has been used. It should be noted that the ATCvet classification systems does not enable the analysis of the distribution of medicines for particular conditions (e.g. diseases), only broad therapeutic categories.

Figure 2.6 shows, for all countries for which data were available, the number of authorised products within each of the first tier ATCvet categories. These data can be used to show therapeutic areas where there are relatively few authorised products, though it was observed by stakeholders that this does not conclusively indicate areas of shortage. Certain therapeutic categories are relatively unimportant within animal health, whilst others – e.g. QB (blood products) – are considered to be emerging areas where developments may take place in the future.

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Figure 2.6 ATCvet categories QP (antiparasitics), QJ (antiinfectives) and QI (immunologicals) accounted for the largest numbers of authorised products, on average making up 63 per cent of the total number of medicines. In smaller markets in particular there were very few authorised products (typically under 5) within many therapeutic categories.

Therapeutic categories (ATCvet system) for all authorised products on national markets, as at May 2010

Source: GHK analysis of MA databases

2.1.4 The number of applications for new MAs submitted each year is low, and few applications concern products aimed at minor species.

Analysis of data on the applications received by the authorities should provide an indication of levels of innovation in the veterinary medicinal products sector, and highlights where gaps are being filled. Data on applications are, however, incomplete, and only the following databases were available:

- Applications submitted through the Centralised Procedure between 1997-2009;
- Applications submitted through the MRP and DCP between 2006-2009; and,
- Applications submitted through the National Procedure in the UK between 2000-2009.

No other competent authorities provided data on applications received through the National Procedure.

The analysis presented here only considers applications for new MAs and for applications to extend existing MAs to new species, since these are measures of innovation within the sector (as opposed to applications for renewals or for administrative variations). Figure 2.7 shows the number of such applications received by the authorities in each year for which data are available.
Figure 2.7  The EMA typically receives around 20 applications for a new MA/line extension through the Centralised Procedure each year. Data as regards applications through the MRP and DCP are limited, but do show that both routes are used more frequently by businesses than the Centralised Procedure. In the UK, applications received through the National Procedure have declined in number in recent years.

The number of applications for new MAs/line extensions received by the authorities through the Centralised (1997-2009), Mutual Recognition (2006-2009), Decentralised (2007-2009) and National (UK only, 2000-2009) Procedures each year

Source: GHK analysis of MA databases

A key issue with respect to the applications data is the extent to which applications for new MAs and line extensions are ‘filling the gaps’ identified previously. Whilst the data are too incomplete to enable a robust analysis of trends in applications over the past few years, some general points can be identified. Figure 2.8 shows the total number of applications for new MAs/line extensions that involved products intended for use with the five minor species (horses, goats, turkeys, bees and salmon, trout and other fish) that were analysed previously (see Figure 2.5). Data on applications received through the National Procedure are only available for the UK, meaning that this is a partial picture of innovation within medicines aimed at minor species.
Figure 2.8  The number of applications for new MAs/ line extensions involving products intended for use with minor species has historically been low, suggesting that the current distribution of authorised products for target species will persist. Of all the applications concerning minor species plotted in the figure below, 62 per cent involved horses and just 4 applications (2 per cent) involved bees.

The number of applications for new MAs/ line extensions involving horses, goats, turkeys, bees, or salmon, trout or other fish received by the authorities through the Centralised (1997-2009), Mutual Recognition (2006-2009), Decentralised (2007-2009) and National (UK only, 2000-2009) Procedures each year.

Source: GHK analysis of MA databases

2.1.5 High proportions of authorised products are not marketed in smaller countries

Analysis of MAs does not indicate which products are actually marketed within countries. Commercial decisions regarding return on investment drive actual product availability, even where a MA holder has spent resources obtaining an authorisation. This is particularly true of the Centralised Procedure, where companies are granted authorisation throughout Europe but may not intend to market the product in all countries.

The authorised product databases provided by competent authorities did not indicate which products are actually marketed. Instead, the availability of authorised products was investigated by collecting data from a sample of MA holders for 5 of the 6 case study countries²⁷. Data were disaggregated between the Centralised, Mutual Recognition and National Procedures (too few products were authorised through the DCP to enable a robust analysis of the results)²⁸. The results are shown in Figure 2.9.

²⁷ A total of 8 of the largest MA holders (measured by the number of MAs held) were asked to indicate which of their authorised products were actually marketed within 5 of the 6 case study countries (at the point at which this exercise was carried out, no data on MAs were available for Germany).

²⁸ The proportion of total MAs in each country that were covered by this exercise was as follows: UK (40% of the total number of MAs); FI (58%); PL (41%); CY (55%); RO (28%).
Figure 2.9 Products authorised through the National Procedure were most likely to be marketed (on average 80 per cent of MAs were marketed). In contrast, on average 56 per cent of products authorised through the Centralised Procedure were marketed, though in Romania the proportion was as low as 34 per cent.

The proportion of a sample of MAs that are marketed in selected countries, as at January 2011

2.1.6 Availability problems mean that medicines sometimes have to be used 'off-label'

In instances where there are no authorised medicines available in a country to treat a particular condition, by way of an exception veterinarians may make use of the prescribing cascade. The cascade enables veterinarians to use medicines ‘off-label’ (i.e. outside of the conditions of authorisation). The term cascade is used as there is a defined order that must be followed:

1. A veterinary medicinal product authorised in the country in question but for use with another species or another condition within the same species;
2. If there is still no suitable medicine available, then either:
   ▪ A medicine authorised for use with humans in the country in question; or,
   ▪ A veterinary medicinal product authorised for use in another EU/EEA country.
3. Then finally:
   ▪ A medicine prepared extemporaneously, by a veterinarian, pharmacist or another person holding an appropriate manufacturer’s authorisation.

The purpose of the cascade is to ensure that even where there are no authorised medicines available, veterinarians can still legally provide treatment for animals. Whilst the preceding analysis has shown areas where there may not be medicines available, this is thus only part of the picture.

As reviewed in Annex 1, the study team sought to collect data on the usage of the cascade. Veterinarians are required to keep records of the usage of the cascade available for inspection by the authorities for at least five years, but there is no requirement to submit these reports to a central authority. The research carried out for this study did not identify a single country where records are collated centrally as to the frequency of usage of the cascade, or how it is being used (e.g. distribution by species, condition etc).
In the absence of data, as part of the stakeholder consultation exercise (see Section 1.1.5), the study team carried out interviews with representatives from regulatory bodies, industry and veterinarian organisations. During these meetings, consultees were asked about the usage of the cascade. Overall, few consultees were able to comment, primarily due to the lack of data on how the cascade is being used.

A number of consultees believed that the option to utilise authorised human medicines was being used in preference to other tiers of the cascade, principally on cost grounds. Human medicines used to treat simple and common conditions are typically cheaper than their veterinary equivalents, and it was suggested that this can act as an incentive to omit the first tier of the cascade and use a human medicine, particularly for companion animals where the risks to human health are generally lower. To varying degrees regulatory authorities have sought to address this issue, for instance by seeking to prevent veterinarians from routinely stocking human medicines.

There are no data available on the impact of the cascade. As a means of protecting animal welfare it is clearly important – without the cascade were the law to be followed then veterinarians would frequently have to resort to euthanasia. Consultees were asked about possible negative impacts:

- Since products are being used ‘off-label’ there are potential negative impacts on animal and human health, for instance unexpected side-effects or problems identifying the correct dosage. However, none of the consultees, including those from regulatory bodies, indicated that this was a serious problem;

- It was noted that the misuse of the cascade could act as a disincentive for companies to invest in new product development or seek to have an authorisation extended into a country where it was presently not available (though were they to do so then the cascade would become illegal). However, none of the consultees from industry indicated that this was a noteworthy problem.

In order to explore the issue of the operation and impact of the cascade in more detail, the study team carried out a case study of the off-label usage of antibiotic footbath in the UK (see Case Study 3). An extended version of the case study, with references, is attached as Annex 10.

**Case Study 3 Off-label usage of antibiotic footbath in the UK**

Lameness in cattle and sheep is one of the biggest causes of economic loss and decreased animal welfare in UK farming. Whilst the incidence of lameness varies between farms, amongst dairy cattle it has been estimated that between 20 per cent and 40 per cent of animals are affected at any one time, and amongst sheep the comparable proportion of affected animals has been estimated to be between 6 per cent and 11 per cent. Two of the most common causes of lameness in cattle and sheep are, respectively, digital dermatitis and contagious ovine digital dermatitis. The spread of digital dermatitis is associated with slurry, passing the organism between the feet of cattle.

Whilst effective farm management can reduce the spread of these two conditions, antibacterial therapy is usually required since they are infectious problems. Individual animals often respond well to topical treatments applied to the foot, such as repeated application of authorised antibiotic sprays. However, rapid recycling of disease through a flock or herd makes treating animals individually time consuming, ineffective and uneconomic. Injectable antibiotic treatments suffer from the same problems, as well as concerns about potential antibiotic residues in milk. Thus whilst there are products authorised in the UK for the treatment of digital dermatitis and contagious ovine digital dermatitis, they may not be appropriate for use at the level of the whole flock or herd.

Foot-bathing is thought to be an effective method of treating a whole flock or herd. There are non-antibiotic footbath treatments available, but these are often ineffective when used alone, and can be extremely painful to animals. As a result, the off-label usage of antibiotic products as footbaths (typically soluble lincomycin, spectinomycin, erythromycin or tylosin) is thought to have become widespread in the UK. Robust data on the levels of usage are unavailable, and the need for antibiotic footbaths tends to be seasonal, and related to the occurrence of disease outbreaks. A 1998 study estimated that between 70 per cent and 100 per cent of dairy farms affected by digital dermatitis used antibiotic footbaths. Elsewhere, suggested regimens have promoted the usage of
antibiotic footbaths every 4-6 weeks during winter, and also whenever new animals are added to the milking herd.

The problems associated with the usage of antibiotic footbaths through the cascade include:

▪ Antibiotic residues within milk are a major concern for the dairy industry, potentially condemning millions of litres of milk. Limited evidence is available on the potential for the systemic absorption of antibiotic products through footbaths, and in any case there is potential for udder contamination. Whilst a minimum withdrawal period is applied, it has been suggested that this may well be flouted for milk (a minimum of 7 days withdrawal);

▪ Antibiotic resistance is becoming a significant concern, especially where routine usage is common. Controlled usage, at the correct dosages, is key to decreasing the build up of resistance. With unauthorised products, there is only anecdotal evidence of the correct concentrations to use, and the correct method of usage (e.g. contact times and topping up of the footbath);

▪ The disposal of footbaths presents a risk (the most common method is mixing with the slurry system), but since the products are being used off-label there are no guidelines available on the safest method of disposal;

▪ This issue highlights the potential complexity with the cascade, since there are technically products available for the control of small numbers of cases, but not for whole flocks or herds. It is thus presently unclear for veterinarians where the line should be drawn when recommending the off-label usage of antibiotic footbaths;

▪ Given the potential size of the ‘market’ for antibiotic footbaths, it is possible that the unlicensed usage of such products is acting as a disincentive for the development of new products.

2.2 There are deficiencies in the operation of the single market

In the absence of a definitive source of information on the operation of the single market in veterinary medicinal products, we must instead draw on other indicators of the extent to which goods can circulate freely throughout the EU. Key issues with the operation of the single market in veterinary medicinal products include the following:

▪ High proportions of products are only authorised on a single national market; and,

▪ High proportions of companies only have MAs on their national market.

These issues are discussed in more detail below. Data on the prices of veterinary medicinal products were sought for a selection of products, in order to assess whether problems with the operation of the single market were manifested in variations in product prices between countries. As discussed in Annex 1, however, data could not be obtained in a format that permitted cross-country analysis.

2.2.1 High proportions of products are only authorised on a single national market

A key measure of the functioning of the single market in veterinary medicinal products is the extent to which products are authorised throughout the EU. In principle, the more national markets that a product is authorised within, the better the operation of the single market. In practice, however, demand factors may mean that this is not the case. In some instances there will be no need for a product, for instance if climatic conditions mean that there is no incidence of a particular disease, or indeed if animal populations are zero (e.g. the absence of Atlantic salmon in southern Mediterranean countries).

With these issues in mind, data on MAs from national authorised product databases were analysed in order to measure the number of national markets (from 1 to 19) that a product was authorised within. It was necessary to measure the number of authorised brands rather than the number of MAs, since the latter could include details of dosages, and the text was typically presented in the language of the country in question. Two methodological issues should be noted. Firstly, the same product could be authorised under a different brand name in different countries, meaning that the total number of brand names is likely to be an overestimation of the ‘real’ number of authorised product brands. Secondly, there are errors in national databases (e.g. products authorised through the Centralised Procedure – which
should by definition feature in all 19 national databases – are missing from some national datasets).

The results of this analysis are shown in Figure 2.10. Taking into account the methodological issues noted above, the data provided by the national competent authorities indicate that there were a total of 5,169 ‘unique’ authorised product brands across the 19 countries that provided data.

**Figure 2.10** The majority of product brands – 67 per cent of the total – were only authorised on a single national market. Just 1 per cent of product brands were authorised throughout the 19 countries for which data were available, though as noted above, authorisations through the Centralised Procedure are not recorded accurately on national databases.

The proportion of product brands authorised on between 1 and 19 national markets, as at May 2010

Source: GHK analysis of MA databases

### 2.2.2 Most companies only have MAs on their national market

An effectively functioning single market would encourage companies to seek MAs for their products throughout the EU, and we would thus expect to see MA holders present within multiple EU countries. Conversely, high proportions of companies only ‘active’ within their national market would suggest that there are disincentives to accessing other EU markets.

Data on MA holders, drawn from national databases on authorised products, can be used to determine the extent to which businesses hold MAs on more than one national market. To recap, 18 countries provided data on the identity of MA holders, which indicated that there were a total of 463 businesses with MAs. The number of national markets within which these businesses held MAs ranged from 1 to 18 (the latter would be the case for any business that had a product authorised through the Centralised Procedure). Figure 2.11 shows the proportion of businesses that held MAs in between 1 and 18 national markets.

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29 It should be noted that this is an imperfect measure since company ownership patterns are not known, and MA holders may be local affiliates of multinational companies
Figure 2.11 The majority of MA holders – 62 per cent – only held MAs in a single national market; just 4 per cent of MA holders held MAs within all 18 national markets for which data were available.

The proportion of MA holders with at least one MA on between 1 and 18 national markets, as at May 2010.

Source: GHK analysis of MA databases

Figure 2.12 shows how this pattern varies among countries. For each national market for which data were available, Figure 2.12 shows the proportion of total MAs that were accounted for by companies that held MAs on between 1 and 18 national markets. The results thus indicate the extent to which national markets contain companies that are also present within other countries or, conversely, whether they contain companies that only ‘active’ on their national market.

Considering Figure 2.11 and Figure 2.12 together suggests that the animal health industry in Europe consists of a small number of companies that hold MAs in multiple national markets, and a large number of companies that only hold MAs on one national market. The former group includes high-profile large multinational pharmaceutical companies, who typically hold large numbers of MAs (those companies that had an MA on all 18 national markets on average each held a total of 838 MAs).

The latter group – companies that were only present on one national market – makes up the majority of the animal health sector in terms of the number of companies (Figure 2.11), but the minority in terms of its share of total Europe-wide MAs (Figure 2.12). These companies on average each held 6 MAs. Of the 463 companies that held an MA as at May 2010, 101 companies – 22 per cent of the total – held a single MA on a single national market.
Figure 2.12 In almost all cases, the majority of MAs on each national market were accounted for by businesses that held MAs in all 18 national markets (i.e. companies that could be considered the most ‘pan-European’ in presence). Notable exceptions were Romania, the Netherlands, Germany, Portugal and the UK, all of which contained sizeable numbers of businesses that only held MAs in those countries.

The proportion of MAs on each national market that were accounted for by MA holders with at least one MA in between 1 and 18 national markets, as at May 2010

Source: GHK analysis of MA databases

2.3 There is a high administrative burden imposed on industry

The regulatory requirements of the legislation – e.g. the conditions that businesses must meet in order to have a produce authorised – impose administrative burdens on industry. The magnitude of these burdens has been measured by the study team through a survey of veterinary pharmaceutical companies, who were asked to calculate the average time required in order to meet each of the legislative requirements (see Section 1.1.3 for details). Using this information, the study team developed a standard cost model (SCM) for veterinary pharmaceuticals, which measures the total EU/EEA-wide annual cost to industry of compliance with regulatory requirements. Further details of the methodology followed to develop the SCM are attached as Annex 2. Administrative burdens are also imposed on other stakeholders (e.g. regulatory bodies), though these lie outside of the SCM and have thus not been measured (though these burdens are considered in qualitative terms as part of the impact assessment in Section 4).

The results of the SCM are summarised below. To place this information in context, the administrative burdens imposed on businesses in the EU/EEA were related to those imposed on businesses in other areas of the world. Potentially, if administrative burdens were significantly higher in the EU/EEA than in other markets, this might affect the international competitiveness of European companies. IFAH-Europe – a trade association for the veterinary pharmaceuticals sector – has commissioned research comparing regulatory burdens between Europe and other key markets. Drawing on a survey of veterinary pharmaceutical companies, a 2007 study[^30] reported that:

86 per cent of European businesses reported that ‘the regulatory framework’ was a barrier to innovation, compared to 86 per cent in the United States, and 93 per cent in Japan;

Businesses were asked to identify which impacts of the regulatory framework presented the biggest barrier:
- 93 per cent of European businesses identified the costs associated with compliance (100 per cent in the United States);
- 93 per cent noted that the regulatory framework increased product development time (also 93 per cent in the United States);
- Other notable impacts reported by businesses included: the creation of uncertainty (86 per cent of European companies), and the re-direction of resources to defensive R&D (93 per cent of European companies).

The impact of the legislative framework on product development time was identified as an important issue for businesses, alongside the costs of complying with the legislation.

2.3.1 Administrative burdens are equivalent to a high proportion of industry turnover

Table 2.1 presents the SCM outputs for veterinary medicinal product legislation (detailed tables of the results are provided in Annex 7). Data are disaggregated across the major Information Obligations. The data shown in Table 2.1 indicate that the single largest administrative burden is the cost of complying with the packaging and labelling requirements of the legislation, which costs industry an estimated EUR 184.4 million per year, equal to 34 per cent of the total administrative burden.

Overall it is estimated that the annual administrative burden incurred by businesses amounts to EUR 537.9 million per year, across the EU/EEA. In 2008, total sales for the veterinary medicines industry in Europe were estimated at EUR 4.3 billion. On this basis, the administrative burden associated with the meeting legislative requirements is currently equivalent to 13 per cent of the annual turnover of the sector.

Table 2.1 The estimated value of the annual administrative burdens imposed by the legislative framework for veterinary medicinal products

<table>
<thead>
<tr>
<th>Information Obligation</th>
<th>Administrative burden (million EUR p.a.)</th>
<th>% of total administrative burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applying for a new MA</td>
<td>Sub-total 91.1</td>
<td>17%</td>
</tr>
<tr>
<td>Applying for a variation to an existing MA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type 1A</td>
<td>19.7</td>
<td>4%</td>
</tr>
<tr>
<td>Type 1B</td>
<td>20.6</td>
<td>4%</td>
</tr>
<tr>
<td>Type 2</td>
<td>93.1</td>
<td>17%</td>
</tr>
<tr>
<td>Sub-total</td>
<td>133.5</td>
<td>25%</td>
</tr>
<tr>
<td>Renewing a MA</td>
<td>Sub-total 69.5</td>
<td>13%</td>
</tr>
</tbody>
</table>

Pharmacovigilance reporting

<table>
<thead>
<tr>
<th>Information Obligation</th>
<th>Administrative burden (million EUR p.a.)</th>
<th>% of total administrative burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspected Adverse Reactions</td>
<td>4.3</td>
<td>1%</td>
</tr>
<tr>
<td>Serious Adverse Reactions</td>
<td>8.0</td>
<td>1%</td>
</tr>
<tr>
<td>PSURs(^{31})</td>
<td>47.2</td>
<td>9%</td>
</tr>
<tr>
<td>Sub-total</td>
<td>59.4</td>
<td>11%</td>
</tr>
<tr>
<td>Packaging &amp; labelling</td>
<td>Sub-total 184.4</td>
<td>34%</td>
</tr>
<tr>
<td>Grand total</td>
<td>537.9</td>
<td>100%</td>
</tr>
</tbody>
</table>

Source: GHK calculations based surveys & engagement with industry and regulators

\(^{31}\) Period Safety Update Reports (PSURs)
Figure 2.13 disaggregates the estimate of administrative burden according to the type of cost. Staff costs measure staff time plus overheads, equipment costs measure internal equipment costs (e.g. IT costs), and outsourced costs measure externalised costs (e.g. drawing on an external expert to complete a technical report).

In most cases, staff costs comprise the majority of the administrative burden incurred by businesses. Equipment costs are typically low, except in the case of packaging and labelling costs. Outsourced costs are relatively large where external expertise is used significantly (e.g. as part of the compilation of a dossier for an application for a new MA).

The value of the administrative burden imposed on businesses by key Information Obligations (EUR million p.a.), disaggregated by staff, equipment and outsourced costs

Source: GHK analysis

2.3.2 Administrative burdens vary by Marketing Authorisation procedure

The SCM can be used to compare the administrative burdens generated by the different MA procedures. Figure 2.14 shows the administrative burden incurred per product per action, disaggregated between the four different MA procedures. For example, on average the administrative burden generated by applying for a new MA through the Centralised Procedure is an estimated EUR 243,729 per application (i.e. per product). The estimated cost of applying for a Type 1A variation through the Centralised Procedure is EUR 8,354 per application (i.e. per product). Of course, it is likely that over the lifetime of a product multiple applications for a Type 1A variation would be submitted, increasing the size of the administrative burden each time.

Data for the Centralised Procedure cover all 30 countries, whilst data for the National Procedure only relate to a single application (i.e. a single country). In practice, the costs of the National Procedure would be likely to vary between countries. The data in Figure 2.14 provide an average figure for the EU/EEA. The administrative burden for the DCP and MRP will vary depending on the number of countries involved and, again, the data show the administrative burden incurred by an average application.
Figure 2.14 Per product, the highest administrative burden per action is incurred when applying for a new MA. Applying for a type 2 variation is typically more expensive than applying to renew a MA. Of the MA procedures, the DCP is the most costly to companies on average, and the Centralised Procedure is the least costly of the three European MA procedures. The National Procedure generates the lowest administrative burden of all procedures, though note that these data are per country.

The average administrative burden (EUR) per product per action, disaggregated by MA procedure

Source: GHK analysis

2.4 Key messages

This section of the report has presented an analysis of the problems currently facing the veterinary medicinal products sector. The key messages are as follows:

Key messages:

- Problems with the completeness and comparability of data mean that it has proven difficult to build a thorough and robust picture of the availability of veterinary medicines in the EU/EEA. We can, however, say with confidence that the sector faces the following problems:
  - There are relatively few products authorised for use in small countries;
  - There are relatively few products authorised for use with certain minor species, particularly bees;
  - There are relatively few authorised products within certain therapeutic areas;
  - Innovation in the sector is tending to reinforce these patterns, with relatively few applications for new authorisations in medicines targeted at minor species;
  - Authorisations provide a partial picture of availability, and evidence suggests that actual levels of product availability are lower in small markets than authorisation data suggest.

- A lack of availability of veterinary medicines can have serious consequences for human and animal health, as the case studies of avian influenza and bluetongue that were presented above have discussed. Without authorised medicines, veterinarians have to resort to using products ‘off-label’ through the cascade in order to treat animals;

- There is evidence of deficiencies in the operation of the single market in veterinary medicinal
products. Whilst there are methodological problems in making the calculation, the data suggest that the majority of veterinary medicines are only authorised within a single EU/EEA country. Similarly, information on MA holders suggests that the majority of companies only operate within a single national market. Despite the opportunities created by the legislation, it appears as though only a relatively small number of businesses actively seek to market their products throughout the EU/EEA;

- Industry representatives attribute this pattern to the regulatory costs imposed by the legislation. The administrative burdens incurred by industry in complying with the requirements of the legislation are estimated to amount to around EUR 537.9 million per year. This is the equivalent to around 13 per cent of the annual turnover of the veterinary pharmaceuticals industry.
3 Policy Objectives and Policy Options

This section of the report commences with an outline of the general and specific objectives of the proposed revisions to the legislative framework for veterinary medicinal products. There then follows a summary of the policy options for the legislative revision, showing how they relate to the achievement of the policy objectives, and providing a description of the details of each option.

3.1 Policy objectives of the legislative revision

Guidelines produced by the European Commission require the development of three ‘tiers’ of policy objectives as part of an impact assessment. These objectives describe the purpose of the legislative revision and should directly relate back to the problem definition set out in Section 2. Policy objectives shape policy options and form the basis against which the impacts of options can be measured and comparisons drawn (and future effects monitored). The three tiers of policy objectives required in an impact assessment are as follows:

- **General objectives**: the treaty-based goals towards which the legislation contributes, and equate to the impacts that the revision of the legislation should seek to achieve;
- **Specific objectives**: the specific aims of the revision of the legislation, and should relate directly to the results of the problem definition. In aggregate the achievement of the specific objectives should contribute towards meeting the general objectives of the legislative revision;
- **Operational objectives**: the direct deliverables of the legislative revision (e.g. outputs), and again when aggregated should contribute towards achieving the specific objectives of the revision exercise.

The **general objectives** of the legislative revision relate directly to the three high-level problems reviewed in Section 2 of this report:

- To improve the functioning of the single market in veterinary medicinal products;
- To enhance the level of protection for humans, animals and the environment (e.g. through increasing the availability of veterinary medicinal products); and,
- To reduce the administrative burden imposed on businesses.

Nested within these general objectives are a set of **specific objectives** for the legislative revision. These objectives address specific aspects and causes of the high-level problems discussed previously, and there are five in total:

- To simplify procedures for obtaining a new MA for a veterinary medicinal product;
- To simplify legislative requirements for products once they have obtained a MA;
- To provide incentives for the development of new veterinary medicinal products;
- To ensure that the legislative framework for veterinary medicinal products is able to meet emerging needs and challenges; and,
- To ensure the effective operation of the legislation.

The relationship between the problem definition, general objectives and specific objectives is shown in Figure 3.15.
The relationship between the results of the problem definition and the general and specific objectives for legislative reform

**Problem definition**
- Insufficient availability of veterinary medicines
- Deficiencies in the operation of the single market
- A high administrative burden imposed on industry

**General objectives**
- To improve the functioning of the single market
- To enhance the level of protection for humans, animals and the environment
- To reduce the administrative burden imposed on businesses

**Specific objectives**
- To simplify procedures for obtaining a new MA
- To simplify legislative requirements for products once they have obtained a MA
- To provide incentives for the development of new veterinary medicinal products
- To ensure that the legislative framework meets emerging needs and challenges
- To ensure the effective operation of the legislation

Table 3.2 reviews in more detail the anticipated results and impacts associated with each of the specific objectives. Results describe the direct short-term effects of the achievement of each objective, whilst impacts describe the longer-term effects that follow on from these results. Impacts are analogous to the achievement of the general objectives of the legislative revision, and address the three high-level problems reviewed in Section 2. For instance, simplifying requirements for obtaining a new MA would directly result in a reduction in the administrative burden imposed on companies, making some marginal product markets more attractive, and creating savings that could potentially be reinvested in new product development. Together these results should increase the availability of medicines, the impact of which would be an improvement in the protection of human and animal health.

<table>
<thead>
<tr>
<th>Specific policy objective</th>
<th>Result(s)</th>
<th>Impact(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>To simplify procedures for obtaining a new MA for a veterinary medicinal product</td>
<td>Savings on administrative burdens lead to increased investment in new product development</td>
<td>Enhanced human and animal health protection through increased availability of medicines</td>
</tr>
<tr>
<td></td>
<td>Reduced barriers to free movement of goods through harmonisation and simplification of requirements for placing medicines on the market</td>
<td>Improved operation of the single market due to reductions in barriers to the free movement of goods</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reduced administrative burden</td>
</tr>
<tr>
<td>To simplify legislative requirements for products once they have obtained a MA</td>
<td>Savings on administrative burdens lead to increased investment in new product development</td>
<td>Enhanced human and animal health protection through increased availability of medicines</td>
</tr>
<tr>
<td></td>
<td>Reduced barriers to free movement of goods through harmonisation and simplification of requirements for maintaining</td>
<td>Improved operation of the single market due to reductions in barriers to the free movement of goods</td>
</tr>
<tr>
<td>Specific policy objective</td>
<td>Result(s)</td>
<td>Impact(s)</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td>To provide incentives for the development of new veterinary medicinal products</td>
<td>Incentives lead to increased investment in new product development</td>
<td>Reduced administrative burden</td>
</tr>
<tr>
<td>To ensure that the legislative framework for veterinary medicinal products is able to meet emerging needs and challenges</td>
<td>Legislation is better suited to the regulation of emerging needs and challenges</td>
<td>Enhanced human and animal health protection through reduced risks posed by emerging needs and challenges</td>
</tr>
<tr>
<td></td>
<td>Harmonisation of divergent national approaches to emerging needs and challenges</td>
<td>Harmonisation of national approaches ensures effective operation of the single market</td>
</tr>
<tr>
<td>To ensure the effective operation of the legislation</td>
<td>Higher standard of implementation of legislation set across the EU/EEA</td>
<td>Enhanced human and animal health protection through higher standard of implementation</td>
</tr>
<tr>
<td></td>
<td>Harmonisation of divergent national approaches to operation of the legislation</td>
<td>Level playing field ensures effective operation of the single market</td>
</tr>
</tbody>
</table>

Finally, as noted above, the operational objectives for the legislative revision describe the quantifiable outputs that are anticipated once the changes have come into force. Operational objectives are considered in Section 5.3 as part of the outline of a monitoring and evaluation framework for the legislative revision.

3.2 Policy options for the legislative revision

Between October 2010 and February 2011 the European Commission developed and finalised a set of policy options for the revision to the legislative framework for veterinary medicinal products. These policy options were based on a number of sources of evidence, including the results of the public consultation exercise that was carried out by the European Commission between March 2010 and July 2010.

Impact Assessment Guidelines stipulate that policy options should clearly relate to the objectives for the legislative revision; that is, there should be a direct and traceable causal relationship between the problem definition, the general and specific objectives, and the policy options.

As a result of the complexity of the legislative framework for veterinary medicinal products and the breadth of the problem definition, the agreed list of policy options for consideration consisted of considerably more options than would typically be the case in an impact assessment. Policy options also addressed specific features of the legislation and are therefore not mutually exclusive. The issue of how these options could be combined into ‘packages’ is considered below. The policy options were as follows:

- A ‘do nothing’ option, whereby the legislation remains in its present form;
- A set of 19 ‘higher level’ policy options addressing a specific feature of the legislation. Most of these higher level options included a set of sub-options, for instance the policy option ‘extend the scope of the Centralised Procedure’ itself consisted of four possible sub-options. In total there were 49 discrete policy options for consideration in the impact assessment.
Table 3.3 lists the 19 higher level policy options, and shows which of the five specific policy objectives for the legislative revision each option is designed to contribute towards. The remainder of this sub-section of the report consists of a description of the content of these policy options and sub-options.

Table 3.3  The impact assessment has considered 19 higher level policy options, each of which contributes towards addressing a specific policy objective

<table>
<thead>
<tr>
<th>Specific policy objective</th>
<th>Higher level policy option</th>
<th>Ref.</th>
</tr>
</thead>
<tbody>
<tr>
<td>To simplify procedures for obtaining a new Marketing Authorisation for a veterinary medicinal product</td>
<td>Extending the scope of the Centralised Procedure</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Making a single national MA valid throughout the EU/EEA</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>Improving the operation of current authorisation procedures</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Simplifying MA procedures for low-risk and generic products</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Reducing data requirements for MAs</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Simplifying requirements for homeopathic products</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>Enabling the free circulation of nationally authorised products</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Simplifying pharmacovigilance requirements</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Simplifying requirements for the renewal of MAs</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Simplifying data recording and reporting requirements</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Simplifying packaging and labelling requirements</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>Simplifying requirements for applying for variations to existing MAs</td>
<td>12</td>
</tr>
<tr>
<td>To provide incentives for the development of new veterinary medicinal products</td>
<td>Amending the scope of the cascade</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>Amending data protection to better reward new product developments, particularly for MUMS uses</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Introducing support for SMEs</td>
<td>15</td>
</tr>
<tr>
<td>To ensure that the legislation is able to meet emerging needs and challenges</td>
<td>Clarifying the scope of the legislation with regard to new types of treatment</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Addressing the potential problem of antimicrobial resistance</td>
<td>17</td>
</tr>
<tr>
<td>To ensure the effective operation of the legislation</td>
<td>Improving harmonisation and oversight of in-market control systems</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>Enforcing a European database of authorised products</td>
<td>19</td>
</tr>
</tbody>
</table>

3.2.2   Option 1: Extending the scope of the Centralised Procedure

At present the Centralised Procedure is mandatory for veterinary medicines developed through biotechnological processes. Moreover, veterinary medicines that contain new active substances or where the product constitutes a significant therapeutic, scientific or technological innovation may be authorised through the Centralised Procedure if the applicant wishes\(^\text{32}\). Usage of the Centralised Procedure, therefore, is currently restricted to a small number of highly innovative products. All MA applications submitted through the Centralised Procedure are assessed by the European Medicines Agency (EMA), which also processes all post-approval authorisation maintenance requirements (variations, renewals, pharmacovigilance etc). Authorisation is granted by means of a Commission Decision, and once a product has been authorised through the Centralised Procedure it may be marketed in all 30 EU/EEA countries.

\(^{32}\) Regulation (EC) No. 726/2004
The purpose of this policy option is to extend the scope of the Centralised Procedure so that it can be used by greater numbers of companies, and for a wider range of product types than is currently the case. There are 4 sub-options as to how this option might operate (summarised in Table 3.4).

Table 3.4 The policy option ‘extending the scope of the Centralised Procedure’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The CP becomes mandatory for all products</td>
<td>Henceforth all new MA applications would be submitted through the CP and assessed by the EMA. Post-approval authorisation maintenance would also be carried out by the EMA. The DCP, MRP and NP would be abolished, though national competent authorities would still be responsible for the maintenance of existing MAs (e.g. processing variations etc).</td>
</tr>
<tr>
<td>1.2</td>
<td>The CP becomes mandatory for all products with new active substances</td>
<td>Products with new active substances would have to be submitted through the CP (it is currently optional for such products). The other MA procedures remain in place.</td>
</tr>
<tr>
<td>1.3</td>
<td>The CP is made available for all products</td>
<td>The other MA procedures remain in place and the CP becomes optional for all products.</td>
</tr>
<tr>
<td>1.4</td>
<td>The CP becomes mandatory for all products requiring specific expertise, and is made available for all products</td>
<td>The other MA procedures remain in place and the CP becomes optional for all products. The list of products that must go through the CP is extended to include all types of product that require specific scientific or technical expertise (as yet undefined).</td>
</tr>
</tbody>
</table>

3.2.3 Option 2: Making a single national MA valid throughout the EU/EEA

At present, outside of the Centralised Procedure, companies must apply for a MA to the competent authorities in each country within which they wish to have a product authorised (the process is simplified through the MRP and DCP but the principle remains the same).

The purpose of this policy option is to simplify this process by making a MA issued by a competent authority in any Member States automatically valid throughout the EU/EEA. Companies seeking to have a product authorised would be free to submit an application to any of the 30 national competent authorities in the EU/EEA. If approved, the company would be granted an authorisation that entitled it to market the product anywhere within the EU/EEA, without any need for further assessments. The process through which compliance with packaging and labelling requirements in each country were assessed would need to be determined, since a national competent authority would not be able to determine compliance with language requirements in all 30 EU/EEA countries.

In terms of post-approval maintenance, applications for variations and renewals, together with all pharmacovigilance reporting, would only be submitted to the national authority that had performed the original assessment.

This policy option includes 2 sub-options, both of which concern possible systems for quality control (summarised in Table 3.5).
Table 3.5 The policy option ‘a single national MA is valid throughout the EU’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>The quality of the work of the competent authorities would be ensured by an independent EU body</td>
<td>An as yet unidentified EU body (potentially an extension of the role of the Food and Veterinary Office – FVO(^{33})) would be responsible for ensuring that national competent authorities were capable of carrying out MA assessments to the required standard. The powers of this body would need to be clarified</td>
</tr>
<tr>
<td>2.2</td>
<td>The quality of the work of the competent authorities would be ensured through a system of accreditation managed by the Member States</td>
<td>Groups of national competent authorities would assess the quality of the MA assessment systems operated by other countries, based on an as yet undefined system of accreditation. An extension and formalisation of the current BEMA programme(^{34}) could form the basis of this system, though the powers available to competent authorities in the event of non-compliance with accreditation standards would need to be defined</td>
</tr>
</tbody>
</table>

### 3.2.4 Option 3: Improving the operation of current authorisation procedures

This policy option concerns the operation of the MRP, DCP and National Procedure. The MRP and DCP both involve joint working between all of the authorities included within a MA application. Under both the MRP and the DCP, a single competent authority performs the role of Reference Member State and is responsible for evaluating a MA application. The competent authorities in all of the other countries in which authorisation is sought by the applicant (the Concerned Member States) must each choose whether to recognise the decision made by the Reference Member State. The DCP is used where a company is seeking to have a product authorised for the first time in more than one EU/EEA country, whereas the MRP can be used to add additional countries to an existing MA.

The purpose of this policy option is to make revisions to this existing MA system in order to improve its efficiency, thus reducing the administrative burden on applicants and the amount of time taken from the submission of an application through to the decision as to whether to grant authorisation. This policy option thus does not involve any significant changes to the design of the MRP or DCP.

There are 3 sub-options to this policy option, as summarised in Table 3.6.

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\(^{33}\) The FVO is currently charged with checking compliance with the requirements of EU food safety and quality, animal health and welfare and plant health legislation. The FVO carries out audits and inspections of national competent authorities to ensure that official control systems are adequate.

\(^{34}\) The Benchmarking of European Medicines Agencies (BEMA) programme consists of a voluntary network of national competent authorities (human and veterinary medicines agencies) and is intended to improve the quality of national regulatory systems through knowledge exchange. For countries undergoing a BEMA exercise, the process consists of self-assessment and peer review, based on visits by a small team of assessors drawn from other competent authorities.
### Table 3.6  The policy option ‘improving the operation of current authorisation procedures’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>Voluntary recognition of MAs on a case-by-case basis by competent authorities</td>
<td>National competent authorities would be able to voluntarily recognise MAs issued by other competent authorities on a case-by-case basis. Companies would still need to submit applications to all authorities from whom authorisation was sought</td>
</tr>
<tr>
<td>3.2</td>
<td>Automatic recognition of MAs by competent authorities</td>
<td>National competent authorities – probably operating as semi-formal ‘blocs’ – would automatically recognise MAs issued by other competent authorities within these ‘blocs’. Companies would only need to submit a single MA application to each ‘bloc’</td>
</tr>
<tr>
<td>3.3</td>
<td>Improved coordination between competent authorities</td>
<td>The efficiency of existing MA procedures is improved through enhanced coordination between competent authorities</td>
</tr>
</tbody>
</table>

#### 3.2.5 Option 4: Simplifying the MA procedures for low-risk and generic products

At present, for the most part the MA process does not distinguish between product types, and all products – regardless of their level of risk – must meet the same requirements if they are to be authorised (there are reduced data requirements for applications for generic products). The basis of this policy option, therefore, would be the division of products into high and low risk categories. Existing MA procedures would remain in place for high risk products. For low-risk products, however, the purpose of this policy option would be to simplify the MA process, on the principle that a full scientific assessment of such products is excessive and overly resource-consuming given their risk profile. There are 2 sub-options to this policy option, as summarised in Table 3.7.

### Table 3.7  The policy option ‘simplifying MA procedures for low-risk and generic products’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1</td>
<td>For low-risk/ generic products a fast-track system of authorisation is introduced</td>
<td>How this fast-track system would work has not yet been defined. At a minimum it would consist of shorter deadlines for the completion of each stage of the MA assessment process, but by extension could also involve reduced information requirements</td>
</tr>
<tr>
<td>4.2</td>
<td>For low-risk/ generic products a system of registration replaces authorisations</td>
<td>This option involves the abandonment of the requirement for a full scientific evaluation of a MA application, and the introduction of a new registration scheme. This registration scheme would consist of an administrative check by the competent authorities in each country for which authorisation was sought by an MA applicant</td>
</tr>
</tbody>
</table>

#### 3.2.6 Option 5: Reducing data requirements for MAs

The submission of a dossier as part of a MA application requires the collection of a large volume of data and other material by the applicant (as set out in Annex I of Directive 2001/82/EC). This information enables the competent authorities to assess the quality, safety and efficacy of the veterinary medicinal product. The purpose of this policy option is to reduce the level of information submitted to the authorities in order to lessen the administrative burden placed on applicants. There are 2 sub-options to this policy option, as summarised in Table 3.8.
Table 3.8  The policy option ‘reducing data requirements for MAs’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>Data requirements for MAs are reduced</td>
<td>Any data requirements as part of the submission of product dossiers that were deemed less necessary would be removed (e.g. in relation to aspects of efficacy and quality data)</td>
</tr>
<tr>
<td>5.2</td>
<td>Under certain circumstances products are granted MAs without the submission of full dossiers</td>
<td>In certain circumstances – e.g. to meet unmet public and/or animal health needs – MAs could be granted by the authorities without the submission of full product dossiers</td>
</tr>
</tbody>
</table>

3.2.7 Option 6: Simplifying requirements for homeopathic products

Homeopathic products are included within the scope of the legislative framework for veterinary medicinal products, meaning that they must be authorised within national markets. However, provided certain conditions are met (e.g. that no specific therapeutic indication appears on the labelling), homeopathic products can make use of a simplified registration scheme. Registration schemes are operated nationally and involve the submission of a relatively limited amount of information. All other homeopathic products must go through a full MA process, similar to other types of veterinary medicinal product.

The purpose of this policy option is to reduce requirements for applications for authorisations for homeopathic products, in order to reduce administrative burdens. There are 2 sub-options to this policy option, as summarised in Table 3.9.

Table 3.9  The policy option ‘simplifying requirements for homeopathic products’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1</td>
<td>Homeopathic products are excluded from the scope of the legislation</td>
<td>Homeopathic products would be considered separately and excluded from the scope of the legislation concerning veterinary medicinal products. Instead homeopathic products could be placed on the market without any need for a Marketing Authorisation</td>
</tr>
<tr>
<td>6.2</td>
<td>The registration procedure for homeopathic products is simplified</td>
<td>The registration procedure for homeopathic products would be simplified further, though no details have yet been established</td>
</tr>
</tbody>
</table>

3.2.8 Option 7: Enabling the free circulation of nationally authorised products

This policy option consists of two separate proposals to overcome barriers to the free circulation of veterinary medicinal products that have already been authorised.

As discussed previously, the number of countries within which products are authorised varies significantly, with large numbers of medicines only authorised within a single country. Each country ‘added’ to these existing MAs requires the submission of a new application, a resource consuming exercise. This policy option thus proposes to simplify this process for existing products that can be proven to be safe, for instance where they can demonstrate a positive pharmacovigilance profile.

Another key barrier to the free circulation of authorised products is the lack of harmonisation of Summaries of Product Characteristics (SPCs). SPCs consist of key pieces of product information and are agreed as part of the authorisation process. Whilst for the Centralised Procedure SPCs will be the same in each country, this may not be the case for the other three procedures. Products authorised through multiple National Procedures, perhaps over long periods of time, may well have different SPCs in different countries. Even under the MRP and DCP there may be variations in the SPCs between countries. These variations may include differences in withdrawal periods, targets species, dosages etc. SPCs are included within product packaging and labelling, meaning that manufacturers must redesign both where SPCs vary between countries.
The CMDv\textsuperscript{35} has initiated a voluntary project to harmonise SPCs authorised through the National Procedure. A sub-group was established and tasked with developing selection criteria for the identification of priority products, and producing proposals for a mechanism and approach towards SPC harmonisation. It is understood that the ‘pilot’ phase of this process is due to be completed in 2011.

There are 2 sub-options to this policy option, as summarised in Table 3.10.

Table 3.10  The policy option ‘enabling the free circulation of nationally authorised products’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.1</td>
<td>Nationally authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment</td>
<td>Products that have been determined to have a record of safe use (e.g. as demonstrated by their pharmacovigilance profile) would be allowed to be marketed through the EU/EEA following an administrative assessment (not a scientific assessment) carried out by each national competent authority</td>
</tr>
<tr>
<td>7.2</td>
<td>Systematically harmonise Summaries of Product Characteristics (SPCs) for nationally authorised products</td>
<td>A programme of SPC harmonisation is carried out by the competent authorities, in order to agree and finalise standard SPCs for all nationally authorised products</td>
</tr>
</tbody>
</table>

3.2.9 Option 8: Simplifying pharmacovigilance requirements

The purpose of pharmacovigilance is to collect data on unexpected or undesirable reactions or events relating to the usage of animal medicines once they have been authorised. The legislation currently requires that MA holders maintain databases of all suspected serious or unexpected adverse reactions, including human adverse reactions. MA holders are required to report suspected serious adverse reactions to the competent authorities as and when they occur. Data on adverse reactions are submitted to the authorities as part of Periodic Safety Update Reports (PSURs), which must also contain a scientific evaluation of the benefit-risk balance of the product. PSURs are intended to keep the authorities informed of the safety of a product once it has been authorised. The frequency with which PSURs must be submitted changes as time passes from their date of authorisation (every 6 months after the first placing on the market, ultimately decreasing in frequency to every 3 years once the product has become established). As well as MA holders, other stakeholders including veterinarians and animal owners are expected to submit data to the authorities in the event of adverse reactions.

For the most part, pharmacovigilance requirements are met post-authorisation, but as part of the MA process, applicants are required to submit to the authorities details of their pharmacovigilance systems, including the identity of the responsible person. This information must be submitted with each new application, and any changes to the systems necessitate an application for variation to the authorisation.

There are 2 sub-options to this policy option, as summarised in Table 3.11.

\textsuperscript{35} The Coordination group for Mutual recognition and Decentralised procedures (veterinary), made up of representatives from medicines agencies in the Member States
### Table 3.11  The policy option ‘simplifying pharmacovigilance requirements’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1</td>
<td>Abolish pharmacovigilance requirements</td>
<td>MA holders and other stakeholders would no longer be required to collect and submit any pharmacovigilance data. Instead, the safety of end users and animals would be ensured through an enhanced system of liability and the provision of more detailed product information to reduce adverse reactions etc.</td>
</tr>
<tr>
<td>8.2</td>
<td>Simplify pharmacovigilance requirements</td>
<td>For established low-risk products, the level of pharmacovigilance reporting would be reduced (e.g. through the abolishment of requirements to submit PSURs). A Pharmacovigilance Master File would be introduced, meaning that MA holders would not need to submit information on their pharmacovigilance system with every MA application, nor would they need to submit multiple variations when their pharmacovigilance systems are changed.</td>
</tr>
</tbody>
</table>

#### 3.2.10 Option 9: Simplifying requirements for renewing Marketing Authorisations

At present, MA holders are required to have authorisations renewed 5 years after the initial MA was granted. After this, no further renewals are required, unless the competent authorities assess that this is necessary based on the pharmacovigilance profile of the product, in which case a request for one further renewal is permitted (5 years after the initial renewal).

There are 2 sub-options to this policy option, as summarised in Table 3.12.

#### Table 3.12  The policy option ‘simplifying requirements for renewing MAs’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.1</td>
<td>Abolish the requirement to renew a MA</td>
<td>MA holders would no longer be required to have a MA renewed once it has been authorised</td>
</tr>
<tr>
<td>9.2</td>
<td>Restrict the requirement to renew a MA to specific cases based on the risk profile of the product</td>
<td>Where a product had a specific risk profile (as yet undefined), when authorising the product the competent authorities could require that the authorisation be renewed after a set period of time (as yet undefined). In all other cases the requirement to renew a MA would be abolished</td>
</tr>
</tbody>
</table>

#### 3.2.11 Option 10: Simplifying data recording and reporting requirements

There are no sub-options to this policy option, an overview of which is provided in Table 3.13.

#### Table 3.13  The policy option ‘simplifying data recording and reporting requirements’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.1</td>
<td>The amount of data that must be recorded and reported is reduced</td>
<td>No details are provided, though this policy option can be assumed to relate to the reduction of information provision throughout the veterinary medicinal products supply chain</td>
</tr>
</tbody>
</table>

#### 3.2.12 Option 11: Simplifying packaging and labelling requirements

Directive 2001/82/EC includes details of packaging and labelling requirements that must be met if products are to be authorised and placed on the market. The legislation stipulates that the competent authorities should approve the immediate and outer packaging of veterinary medicinal products as part of the authorisation process (through the submission of mock-ups). Products should generally contain a package leaflet with further product information, which again has to be approved by the competent authorities as part of the authorisation process. The legislation currently stipulates that all packaging and labelling material should...
be in the official language or languages of the country in which it is to be marketed (the possibility of an exception is allowed where the product is to administered by a veterinarian).

The purpose of this policy option is to simplify requirements as regards packaging and labelling, since these constitute a significant administrative burden. There are 3 sub-options to this policy option, as summarised in Table 3.14.

Table 3.14 The policy option ‘simplifying packaging and labelling requirements’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.1</td>
<td>Prior approval of packaging and labelling by the authorities is abolished</td>
<td>The submission of mock-ups as part of the MA application process is abolished, and the authorities may not longer pre-approve packaging and labelling</td>
</tr>
<tr>
<td>11.2</td>
<td>The amount of text required on packaging and labelling is reduced</td>
<td>Where possible pictograms are used on packaging and labelling in order to reduce the amount of text that MA holders must print</td>
</tr>
<tr>
<td>11.3</td>
<td>The authorities may authorise the use of non-official languages on packaging and labelling in their territory</td>
<td>The authorities can authorise the use of a non-official language on packaging and labelling in their territory</td>
</tr>
</tbody>
</table>

3.2.13 Option 12: Simplifying requirements for applying for variations to existing Marketing Authorisations

Any amendment to the formal documentation and/or underlying data submitted in support of a MA requires the submission by the MA holder of a variation application to the relevant competent authorities. The number of competent authorities to whom variation applications have to be submitted depends on the procedure followed, and ranges from one (the EMA in the case of the Centralised Procedure), up to all 30 EU/EEA countries in the (unlikely) event that a product was authorised through 30 individual National Procedures. Variations are categorised according to their complexity, ranging from Type 1A variations (the least complex), through Type 1B variations, to Type 2 variations (the most complex). In recent years attempts have been made to simplify arrangements for variations, and since 2009 variations legislation has been harmonised across all four MA procedures. Under the ‘new’ system, Type 1A variations (e.g. administrative changes, such as a change in the name and/or address of the MA holder) can be implemented by a MA holder before the competent authorities are notified, and such notifications can take the form of annual reports which ‘bundle’ together multiple variations.

This policy option currently consists of a proposal to extend the scope of the simplification exercise to include other types of variation deemed to be administrative in nature, and not affecting health protection issues. How far these proposals would go beyond the current Type 1A designation has not yet been defined.

There are no sub-options to this policy option, an overview of which is provided in Table 3.15.

36 Approaches towards variations submitted through the CP, MRP and DCP were harmonised in 2008 with Commission Regulation (EC) No.1234/2008, and in 2009 variations submitted through the National Procedure were included within this framework through Directive 2009/53/EC, the deadline for the transposition of which was 20 January 2011.
Table 3.15  The policy option ‘simplifying requirements for applying for variations to existing Marketing Authorisations’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.1</td>
<td>Simplifying variations requirements</td>
<td>The current simplification of variations reporting could be extended to include other submissions deemed to be administrative in nature (as yet undefined)</td>
</tr>
</tbody>
</table>

3.2.14 Option 13: Amending the scope of the cascade

The cascade describes the provision within the legislative framework for veterinary medicinal products for medicines to be used outside of the conditions of their authorisation. At present the cascade can only be used ‘by way of an exception’, in particular to avoid the unacceptable suffering of animals. The purpose of the cascade, therefore, is to act as a ‘safety valve’ in the event that a veterinarian is unable to treat a specific condition in an animal due to the unavailability of an authorised medicine. The term cascade is used because the provision consists of a sequential approach through which an unauthorised medicine can be used, the key tiers of which are as follows:

4. A veterinary medicinal product authorised in the country in question but for use with another species or another condition within the same species;

5. If there is no such product available, then:
   - A medicine authorised for use with humans in the country in question; or,
   - A veterinary medicinal product authorised for use in another EU/EEA country.

There are 3 sub-options to this policy option, as summarised in Table 3.16.

Table 3.16  The policy option ‘amending the scope of the cascade’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.1</td>
<td>Abolish the cascade</td>
<td>The option to make use of unauthorised medicines by way of an exception is abolished – medicines may only be used in accordance with the conditions of their authorisation</td>
</tr>
<tr>
<td>13.2</td>
<td>Reduce the scope of the cascade</td>
<td>Current proposals for reducing the scope of the cascade include restricting its usage to minor species, or only allowing it to be used for animal welfare reasons</td>
</tr>
<tr>
<td>13.3</td>
<td>Increase the scope of the cascade</td>
<td>In this case the scope of the cascade would be increased, such that it could be used in – as yet undefined – eventualities beyond ‘by way of an exception’</td>
</tr>
</tbody>
</table>

3.2.15 Option 14: Amending data protection to better reward new product developments

Data protection is used in order to encourage innovation by rewarding MA holders with a period of exclusivity during which time a generic version of their product cannot be authorised. The data protection period starts from when a product first receives authorisation, and currently lasts for 8 years (13 years for fish and bees). In order to encourage further innovation once a product has been authorised (e.g. the extension into a new species), MA holders receive an extra year of data protection per new food-producing species added to an existing MA, provided additions are made within 5 years of the initial authorisation, and up to a total of 13 years.

This policy option consists of several relatively similar possibilities for revising the data protection period ‘formula’. There are 10 potential sub-options, an overview of which is provided in Table 3.17.
### Table 3.17  The policy option ‘amending data protection to better reward new product developments’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.1</td>
<td>The maximum period of data protection is extended to 16 years</td>
<td>The period of data protection (from the initial authorisation) is extended from 8 to 16 years, for all species</td>
</tr>
<tr>
<td>14.2</td>
<td>The maximum period of data protection is extended to 20 years</td>
<td>The period of data protection (from the initial authorisation) is extended from 8 to 20 years, for all species</td>
</tr>
<tr>
<td>14.3</td>
<td>An extra 3 years of protection is added for each extension to a MA, up to a maximum of 20 years</td>
<td>The present +1 year of data protection per extension (e.g. a new species or new indication) is extended to +3 years per extension, and the requirement that this happen within 5 years of the initial authorisation is abolished</td>
</tr>
<tr>
<td>14.4</td>
<td>An extra 3 years of protection is added for each ‘major’ extension, and an extra 1 year is added for each ‘minor’ extension, up to a maximum of 20 years</td>
<td>The present +1 year of data protection per extension (e.g. a new species or new indication) is extended to +3 years per ‘major’ extension (e.g. a new species), whilst the +1 year if data protection is retained for ‘minor’ extensions. An independent scientific committee assesses whether extensions are ‘major’ or ‘minor’</td>
</tr>
<tr>
<td>14.5</td>
<td>Rewards for new product developments are decoupled from the initial authorisation</td>
<td>The requirement that extensions are authorised within 5 years of the initial authorisation to receive data protection is abolished. Extensions receive the standard 8 years data protection, starting from whenever they are authorised, and irrespective of the position of the ‘original’ authorisation</td>
</tr>
<tr>
<td>14.6</td>
<td>The data protection period for environmental risks is changed to match that for safety and efficacy data</td>
<td>Safety and efficacy data submitted as part of an application is currently protected for 8 years, but environmental data are currently protected for an unlimited period of time, thus ensuring that generics applicants have to provide their own environmental data</td>
</tr>
<tr>
<td>14.7</td>
<td>The period of data protection for fish, bees and other specific species/indications is extended to 16 years</td>
<td>Data protection for fish and bees is extended from 13 to 16 years, and other minor species/uses (as yet undefined) can be included within this designation</td>
</tr>
<tr>
<td>14.8</td>
<td>The period of data protection for fish, bees and other specific species/indications is extended to 20 years</td>
<td>Data protection for fish and bees is extended from 13 to 20 years, and other minor species/uses (as yet undefined) can be included within this designation</td>
</tr>
<tr>
<td>14.9</td>
<td>MA extensions for small markets are rewarded with an extra 2 years of protection, up to 16 years</td>
<td>The present +1 year of data protection per extension is replaced by +2 years provided the extension is into a small market (as yet undefined), and the maximum period of data protection is extended to 16 years</td>
</tr>
<tr>
<td>14.10</td>
<td>MA extensions for small markets are rewarded with an extra 2 years of protection, up to 20 years</td>
<td>The present +1 year of data protection per extension is replaced by +2 years provided the extension is into a small market (as yet undefined), and the maximum period of data protection is extended to 20 years</td>
</tr>
</tbody>
</table>

#### 3.2.16 Option 15: Introducing support for SMEs

Support measures for SMEs\(^{37}\) are already provided by the EMA, and include:

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\(^{37}\) As defined in Commission Recommendation 2003/361/EC, and based primarily on turnover and employment ceilings
• A dedicated SME office within the EMA that provides assistance to SMEs, including advice on procedural matters, together with workshops and SME training courses;

• Financial incentives, such as fee exemptions, fee reductions, and fee deferrals. For instance, for SMEs the fee for an application for a new MA through the Centralised Procedure is deferred until a final decision is issued or the application is withdrawn, meaning that SMEs do not have resources tied up in applications awaiting a decision (which can take months or years).

Under this policy option, support measures such as those provided by the EMA would be rolled out across the EU/EEA, to the benefit of all SMEs, regardless of the MA procedure followed.

There are no sub-options to this policy option, an overview of which is provided in Table 3.18.

| Table 3.18  The policy option ‘introducing support for SMEs’ |
|---|---|
| Ref. | Policy option | Details of policy option |
| 15.1 | Introducing support for SMEs | National competent authorities across the EU/EEA would introduce SME support measures, potentially similar to those already provided by the EMA (e.g. advice, fee reductions etc). |

3.2.17 Option 16: Clarifying the scope of the legislation with regard to new types of treatment

The application of new technologies within the veterinary pharmaceutical industry generates new types of treatment, for instance new formulations and new routes of administration. Current examples include the application of gene therapy and the emergence of blood products, and over the coming years further innovations are to be anticipated. At present these new types of treatment are not properly defined within the legislation, causing confusion as to how they should be treated as part of the authorisation process.

There are no sub-options to this policy option, an overview of which is provided in Table 3.19.

| Table 3.19  The policy option ‘clarifying the scope of the legislation with regard to new types of treatment’ |
|---|---|
| Ref. | Policy option | Details of policy option |
| 16.1 | Clarifying the scope of the legislation with regard to new types of treatment | The scope of the legislation with regard to new types of treatment, including definitions, will be clarified in order to decrease uncertainty |

3.2.18 Option 17: Addressing the potential problem of antimicrobial resistance

The current legislative framework for veterinary medicinal products requires the submission of data on the potential emergence of resistant organisms and the relevance for human health as part of an application for a MA. The mechanism of resistance development is considered particularly important, and where necessary measures have to be proposed to limit any resistance development from the intended veterinary use.

There are 5 proposed sub-options for addressing antimicrobial resistance through the legislative framework for veterinary medicinal products (0).
Table 3.20 The policy option ‘addressing the potential problem of antimicrobial resistance’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.1</td>
<td>Critical antimicrobials for human use are prohibited for use in the veterinary sector</td>
<td>Antimicrobial products identified as critical for use with humans would be prohibited within the veterinary sector, including for use through the cascade</td>
</tr>
<tr>
<td>17.2</td>
<td>Potential impacts on antimicrobial resistance are addressed as part of the MA process</td>
<td>The potential effects of antimicrobial products on the development of resistance would form part of the MA assessment process</td>
</tr>
<tr>
<td>17.3</td>
<td>Veterinarians are prohibited from selling antimicrobials</td>
<td>Veterinarians would only be permitted to prescribe the usage of antimicrobials, and would be prohibited from selling such medicines (a role that would instead be fulfilled by pharmacists, for example)</td>
</tr>
<tr>
<td>17.4</td>
<td>A system is established for collecting data on the sales and usage of antimicrobials</td>
<td>A harmonised EU/EEA wide system for collecting and reporting data on the sales and usage of antimicrobials would be established</td>
</tr>
<tr>
<td>17.5</td>
<td>Controls on the advertising and marketing of antimicrobials to veterinarians</td>
<td>The advertising and marketing of antimicrobials to veterinarians by companies would be subject to stricter controls</td>
</tr>
</tbody>
</table>

3.2.19 Option 18: Improving harmonisation and oversight of in-market control systems

The enforcement of the legislative framework for veterinary medicinal products is the responsibility of the national competent authorities, and there is presently little in the way of harmonisation between countries, or coordinated oversight of national in-market control systems (beyond the control of residues of veterinary medicines). Under this policy option, the role of the Commission in this respect would be strengthened, with enhanced powers to act where national control systems did not meet harmonised standards. Improved coordination of control systems is particularly important should other policy options be introduced which limit or remove the ability of competent authorities to authorise all products that are placed on their respective national markets (see Section 3.2.2 and Section 3.2.3).

There are two sub-options to this policy option, as summarised in Table 3.21.

Table 3.21 The policy option ‘improving harmonisation and oversight of in-market control systems’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.1</td>
<td>National control systems are required to meet agreed European standards, and the Commission has the powers to check such systems</td>
<td>No details are available on the content of the standards that would be applied, but would presumably be an extension of the principle currently applied for the assessment of national control systems for residues of veterinary medicines, and would grant the Commission powers to act where inspections of national control systems identified weaknesses</td>
</tr>
<tr>
<td>18.2</td>
<td>Harmonised EU sanctions are introduced for non-compliance</td>
<td>No details regarding the form or magnitude of the harmonised sanctions are available, but would presumably consist of standardised fines (depending on the type of non-compliance by businesses)</td>
</tr>
</tbody>
</table>

3.2.20 Option 19: Enforcing a European database of authorised products

Whilst an online platform for a European database of veterinary medicinal products already exists (EudraPharm38), it currently only contains details of products authorised through the Centralised Procedure and products authorised by the competent authorities in the UK.

38 http://eudrapharm.eu/eudrapharm/welcome.do
Where uploaded, product records contain detailed information covering the target species, ATCvet code, MA holder, route of administration etc.

This policy option thus does not necessarily require the creation of a new database, but instead involves the compulsory uploading of data on MAs by the competent authorities that have not yet done so. This study involved the collection of data from national authorities on MAs and, as discussed in Section 1.1.3 and summarised in Annex 1, there are presently substantial differences between countries in the coverage of national datasets and protocols for recording authorisation data. This policy option would thus also need to involve the harmonisation of data recording systems.

There are no sub-options to this policy option, an overview of which is provided in Table 3.22.

Table 3.22  The policy option ‘enforcing a European database of authorised products’

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Details of policy option</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.1</td>
<td>Enforcing a European database of authorised products</td>
<td>National competent authorities are obliged to upload their product authorisation databases to the EudraPharm platform, based on harmonised data recording systems</td>
</tr>
</tbody>
</table>

3.3 Key messages

This section of the report has reviewed the policy objectives for the revision to the legislative framework for veterinary medicinal products, and has provided an overview of the policy options that have been included in the Impact Assessment. The key messages are as follows:

Key messages:

- The general objectives of the legislative revision relate directly to the three high-level problems reviewed in Section 2 of this report:
  - To improve the functioning of the single market in veterinary medicinal products;
  - To enhance the level of protection for humans, animals and the environment (e.g. through increasing the availability of veterinary medicinal products); and,
  - To reduce the administrative burden imposed on businesses.

- Nested within these general objectives are a set of specific objectives for the legislative revision. These objectives address specific aspects and causes of the high-level problems, and there are five in total:
  - To simplify procedures for obtaining a new MA for a veterinary medicinal product;
  - To simplify legislative requirements for products once they have obtained a MA;
  - To provide incentives for the development of new veterinary medicinal products;
  - To ensure that the legislative framework for veterinary medicinal products is able to meet emerging needs and challenges; and,
  - To ensure the effective operation of the legislation.

- The European Commission has developed a total of 19 high level policy options for addressing these general and specific objectives. Nested within many of these high level options are specific sub-options. In total, 49 sub-options for the legislative revision have been identified, the impacts of which are considered in the following section of the report (Section 4).
4 The Impacts of the Policy Options

This section of the report presents an overview of the results of the impact assessment of each of the policy options discussed in Section 3. Detailed option-by-option impact assessments are provided in Annex 12. The section concludes with a summary table comparing the impacts of each policy option.

4.1 Approach to measuring options’ impacts

The purpose of the impact measurement exercise is to provide the evidence needed in order to compare the policy options and identify the most advantageous approach. The first stage within an impact assessment process is the identification of the impacts that will be considered. These impacts should link directly to the policy objectives for the legislative revision (set out in Section 3.1), in order to enable an assessment of the extent to which the policy options address the problems that have been identified (as reviewed in Section 2).

The policy options for the revision of the legislative framework for veterinary medicinal products have been assessed against four criteria:

- **The free movement of goods**: there are deficiencies in the operation of the single market in veterinary medicinal products, and this criterion measures the extent to which policy options remove barriers to the free movement of goods within the EU/EEA;

- **The protection of human and animal health**: ensuring a high level of human and animal health protection is a key requirement of the legislation, and this criterion measures the extent to which policy options do or do not improve the current position. For the most part the protection of the health of humans and animals is synonymous, but there are instances where this is not the case, primarily in relation to the policy options addressing potential antimicrobial resistance;

- **The availability of veterinary medicines**: a lack of availability of veterinary medicinal products, particularly within certain market segments, has been identified as a key problem, and so this criterion measures the extent to which policy options are likely to lead to increased availability. Availability can mean both an increase in MAs, and an increase in the marketing of authorised products;

- **The scale of the administrative burden**: this criterion measures the impact on the administrative burdens imposed on all stakeholder groups (industry, regulators and ‘end users’, such as veterinarians). Where administrative burdens are quantified through the application of the SCM, only the scale of the burdens on industry are measured.

As summarised in Section 1.1.5, the assessment of the impacts of the policy options has been based on evidence collected through an extensive stakeholder consultation exercise, involving a range of representatives from industry, regulators and end user groups. The material collected includes a range of qualitative and quantitative evidence.

The remainder of this section of the report consists of a summary of the anticipated impacts of each policy option (see Section 3.2 for a description of the content of the options). Each summary consists of a review of the views of stakeholders, drawing on material collected through the stakeholder survey, and through the consultation exercise that was carried out (see Section 1.1.5). Where relevant, the review also includes the SCM for the policy option, and a comparison of the administrative burdens generated by each policy option and the pre-change ‘baseline’ position (as reviewed in Section 2.3).

Detailed appraisals of the impacts of each policy option are contained in Annex 12, which should be read in conjunction with this section of the report.
4.2 Option appraisals

4.2.1 Option 1: Extending the scope of the Centralised Procedure

4.2.1.1 Sub-option 1.1: The Centralised Procedure becomes mandatory for all products

There was little support amongst consultees and survey respondents for this policy option, despite the fact that it would create a single market for veterinary medicinal products. The main concern expressed by industry representatives was that it would create a significant administrative burden. Businesses wishing to have a product authorised on only a single national market (and data suggest that this is still common) would still be required to have a product authorised in all EU/EEA countries, and bear the burden of translating material into all languages. It was suggested that this would be particularly burdensome for SMEs.

Application of the SCM suggests that the administrative burden would indeed increase under this policy option (by an estimated EUR 170.8 million per year).

Although in principle this policy option would lead to increased availability of medicines, as all new products would be authorised throughout the EU/EEA:

- Data suggest that just because a product is authorised does not mean that it is actually available, and to increase availability this policy option would need to be combined with, for instance, amendments to packaging and labelling requirements;
- Business consultees suggested that there would be a significant decrease in new MA applications were the Centralised Procedure to be made compulsory, caused by the high relative cost. This in turn would also affect product availability (particularly in smaller markets where the additional cost would have a more significant impact on the return on investment).

The process currently followed through the Centralised Procedure would need to be changed were this policy option to be implemented. A number of consultees from all stakeholder groups argued that the EMA would be unable to process the volume of applications that it would receive with its current capacity and procedures.

4.2.1.2 Sub-option 1.2: The Centralised Procedure becomes mandatory for all products with new active substances

This policy option is expected to have a negligible impact. Consultees and survey respondents generally argued that most products with new active substances are authorised through the Centralised Procedure already.

Industry representatives suggested that companies should always have the choice as to where products were authorised, and thus that the compulsory use of the Centralised Procedure might act as a disincentive to invest. A number of consultees from regulatory bodies, however, suggested that the presence of a new active substance in a product means that a high and consistent level of scientific expertise is needed as part of the assessment process, a role best performed by the EMA.

4.2.1.3 Sub-option 1.3: The Centralised Procedure is made available for all products

Whilst welcoming the increased flexibility that an extension of the scope of the Centralised Procedure would bring, representatives from industry generally did not expect there to be a significant uptake in the usage of this authorisation procedure. As discussed previously, there is a widespread perception amongst businesses that the Centralised Procedure is relatively expensive and time consuming, and forces businesses to obtain authorisations for countries within which they have no intention of marketing their products.

It is estimated that the implementation of this policy option would actually result in savings of EUR 5.6 million per year, since SCM data indicate that the MRP and DCP are typically more costly for companies.

Regulators also noted concerns about the extent to which the EMA would have the capacity to process a large numbers of applications should there be a significant increase in usage of the Centralised Procedure. It was also suggested that the structures in place for the
Centralised Procedure – whilst suited to innovative medicines – would not be appropriate for the full range of product types that could potentially be received were the scope of the Centralised Procedure to be extended. These might include relatively well-established medicines that would not require specific scientific expertise.

4.2.4 Sub-option 1.4: The Centralised Procedure becomes mandatory for all products requiring specific expertise, and is made available for all products

Elements of this policy option are already effectively in place, in that most innovative products (which would require ‘specific expertise’) are already authorised through the Centralised Procedure. Representatives from regulatory bodies largely supported the proposal to make this position mandatory, given the level of scientific expertise within the EMA and the consistent application of this expertise across MAs.

Industry stakeholders suggested that there would not be a notable increase in the use of the Centralised Procedure if it was extended to all product types. Consequently, the impact on the administrative burden is estimated to be relatively small (a decrease of EUR 5.6 million per year).

4.2.2 Option 2: Making a Marketing Authorisation valid throughout the EU/EEA

4.2.2.5 Sub-option 2.1: The quality of the work of the competent authorities would be ensured by an independent EU body

This option would result in the creation of a single market for veterinary medicinal products, with a single authorisation entitling a company to market their product throughout the EU/EEA. Representatives from industry were strongly in favour of it, as were consultees from end user groups – who expected it to lead to increased availability of medicines.

The abolition of the need for multiple authorisations for a single product would have a significant effect on the administrative burdens imposed by the legislation, cutting an estimated EUR 67.9 million each year from the administrative burdens on the sector.

Many regulators expressed concern about the devolution of the assessment process to a single country. The key concern, of course, is trust, and the extent to which countries are confident that standards are high enough in all EU/EEA countries to give comfort to others that all authorised products are indeed safe. The proposed independent EU body was seen to provide some assurance that this would be the case, though this body would only be able to assess the quality assurance systems of the organisations that were responsible for carrying out assessments. As several stakeholders noted, the EU body would not be able to ensure the quality of individual MA assessments, which might well vary. Unlike the European procedures currently in use, this policy option does not include any element of peer review which, whilst it requires additional resources and takes time, does provide quality assurance at the level of an individual MA assessment.

4.2.2.6 Sub-option 2.2: The quality of the work of the competent authorities would be ensured through a system of accreditation managed by the Member States

Option 2.2, like Option 2.1, this would create a single market for veterinary medicinal products, and as such is supported by representatives from both industry and end user groups (as it could increase the availability of medicines). The implementation of this policy option would lead to savings in administrative burdens estimated at EUR 67.9 million per year.

Representatives from regulators – and indeed other stakeholder groups – were largely supportive of this policy option, since it devolves management of the proposed quality assurance system to the Member States (rather than relying on an EU body).

As with Option 2.1, the key issue is the level of trust between competent authorities, and the extent to which they are willing to accept authorisations carried out by other authorities. Under this option, quality assurance would be provided by a system of accreditation which would ensure that competent authorities met the necessary standards. Member States would manage this system, presumably following the BEMA programme model whereby small teams of individuals from competent authorities carry out visits and assessments of
other competent authorities. BEMA is, however, voluntary and aims to share good practice; the accreditation system proposed under this policy option would need to have the power to remove the right to carry out EU/EEA-wide authorisations from Member States that did not meet the agreed standards.

4.2.3 Option 3: Improving the operation of current authorisation procedures

4.2.3.7 Sub-option 3.1: Voluntary recognition of MAs on a case-by-case basis by competent authorities

This option is not expected to have a significant impact on the problem. It attracted very little support from industry representatives, who suggested that it would not differ substantially from the present situation. It was felt that there would still be differences of opinion between Member States, which would limit the extent to which time savings were achieved. Consultees and survey respondents from regulatory bodies were relatively neutral about this policy option, but again did not feel that it would differ markedly from the present position.

4.2.3.8 Sub-option 3.2: Automatic recognition of MAs by competent authorities

This option creates a single market within limited group(s) of countries who would automatically recognise the assessments made by other group members. Though the composition of these groups would need to be determined, it is reasonable to assume that in practice they would be formed by the countries that participate most frequently within the MRP and DCP. In such cases the costs to businesses of obtaining a MA would be reduced significantly, since a single application would be sufficient for multiple markets.

The establishment of groups of Member States would require considerable trust between countries (industry representatives raised the current lack of trust as an issue with this policy option). As such, however, this option would probably be less problematic than the policy option which would make authorisations valid in all countries (Option 2), since Member States would be able to restrict this to the countries where they most trusted the capacity and competence of the relevant authorities.

As noted by industry representatives, however, this option would result in the partial establishment of a single market, and would most likely exclude those countries where the resources committed to authorisation systems were lowest, and whose history of participation in European procedures was shortest. If this were the case, the impact of this policy option on gaps in medicine availability would be limited.

Regulators also raised concerns about an assessment being carried out by a single authority, with no peer review of the results. It was suggested that this could present a risk to the protection of human and animal health.

4.2.3.9 Sub-option 3.3: Improved coordination between competent authorities

Stakeholders from all groups felt that this policy option would have very little impact. It was noted that the European procedures already involve a certain degree of cooperation between competent authorities, but that this has not significantly reduced the scale of the administrative burden or the time taken for products to be authorised.

Industry representatives noted that the volume of referrals under the European procedures highlights the frequency with which there are differences of opinion between competent authorities, and that attempts to improve coordination would ultimately have no impact if competent authorities continued to reject the assessments made by others.

4.2.4 Option 4: Simplifying MA procedures for low-risk and generic products

4.2.4.10 Sub-option 4.1: For low-risk/generic products a fast-track system of authorisation is introduced

A number of industry representatives were in favour of a fast-track system whereby an application would be processed quickly in return for a higher fee (since the costs of delays in being able to place a product on the market can outweigh the cost of having a product
authorised), but stressed that this option should be open to all products, not just low-risk and generic products.

There was resistance from some industry consultees to any proposal that would further reduce the costs/time taken for the authorisation of a generic product, since it was felt that this would distort the market in favour of generics.

Representatives from regulatory bodies expressed concern about the thoroughness of a fast-track assessment, and the extent to which this might compromise the protection of health. Given these concerns and the current frequency with which there are differences of opinion between Member States, it was also noted by consultees that products authorised through the fast-track system may well face problems where the MA holder seeks to have the authorisation extended into another country, or where the authorisation is used as the reference case for a generic product.

4.2.4.11 Sub-option 4.2: For low-risk/generic products a system of registration replaces authorisations

There was limited support for this policy option from regulatory bodies who responded to the survey and in consultation. Many regulators were concerned about the impact of this option on the protection of human and animal health, noting that generics products were not necessarily low-risk, and that the full scientific assessment process was a necessary way of ensuring the efficacy and quality of products.

Industry representatives also expressed concern about the impact of this option on the market. Some argued that it would distort the market in favour of generics and in favour of products that had received authorisations at a time when standards were lower (and thus the assessment was cheaper).

Despite these concerns this option could reduce administrative burdens imposed on companies by around EUR 181.9 million per year. Regulators would also have a reduced workload under a registration system.

Representatives from end user groups were more in favour of this policy option since it would probably increase competition and thus lower prices within key product areas. Smaller countries would presumably become more attractive markets if the cost of obtaining an authorisation was reduced significantly.

4.2.5 Option 5: Reducing data requirements for authorisations

4.2.5.12 Sub-option 5.1: Data requirements for product authorisations are reduced

The data reductions proposed under this policy option were not specified, and consequently consultees and survey respondents were unable to comment in detail on the impacts that might be generated. It was also impossible to measure the impact of this option on administrative burdens.

Stakeholders agreed that there was scope to reduce administrative data requirements, which were largely seen to be unduly onerous. Most consultees and survey respondents noted that data requirements in the veterinary sector tend to replicate the position for human pharmaceuticals, and that there was scope for reductions given the differences between the two sectors.

There was no consensus amongst stakeholders as regards whether the amount of efficacy and safety data could be reduced. Representatives from industry wished to see a reduction in the information submitted, arguing that requirements went beyond what was actually needed in order to assess risk, and that there was extensive ‘gold plating’. Most regulators, however, did not support any reductions in data relating to safety, quality and/or efficacy, noting that the approval of medicines had to be based on these criteria.

A consultee from a regulatory body suggested that safety, quality and/or efficacy data could be reduced provided there was sufficient information to accurately assess the benefit-risk balance of the product. On that model data requirements would vary between product types,
and it might be possible to allow reduced data reporting for products deemed to be lower-risk (following the model currently used with MUMS products).

A number of consultees and survey respondents suggested that there are variations in data requirements between countries, and that this lack of harmonisation increases costs and uncertainties, and acts as a barrier to the free movement of goods.

4.2.5.13 **Sub-option 5.2: Under certain circumstances products are granted authorisations without the submission of full dossiers**

Most consultees and survey respondents were in favour of this policy option in principle. It could facilitate rapid response to outbreaks of new epidemics, and thus have a significant positive impact on the protection of human and animal health. Whilst the ability to grant authorisations in exceptional circumstances already exists to some extent, this option would harmonise the procedure to be followed, thus reducing uncertainty.

However, consultees and survey respondents from industry stressed that the circumstances under which reduced dossiers could be submitted should be strictly defined, and that this policy option should not become a way in which companies could bypass the MA process and secure a competitive advantage in the marketplace.

4.2.6 **Option 6: Simplifying requirements for homeopathic products**

4.2.6.14 **Sub-option 6.1: Homeopathic products are excluded from the scope of the legislation**

Opinion was divided on this policy option. Some stakeholders argued that any product making medicinal claims should be treated as a medicine and included within the scope of the legislation. Others argued that the current legislative framework is unsuitable for homeopathic products, which instead need their own legislation.

A representative of a company that manufactured homeopathic products argued that including such products within the legislation ensured that they meet certain quality standards, and that to remove homeopathic products from the legislation would lower standards within the industry and open the market to competition from low quality products. This would have a negative impact on the protection of health.

4.2.6.15 **Sub-option 6.2: The registration procedure for homeopathic products is simplified**

Homeopathic products are already subject to a simplified registration system and are not required to undergo the full scientific assessment process applied to other medicinal products. This policy option would involve a further simplification of this registration scheme, though the details of the simplification would undefined.

The stakeholders contacted for this study were largely in agreement that, whilst homeopathic products are a special class of product, if they make medicinal claims then they should be treated as medicines. Any further simplification of the requirements should not compromise the principle that medicinal claims must be provable (efficacy), and that quality should be ensured.

A representative of a company that manufactured homeopathic products supported the simplification of the registration scheme for homeopathic products, arguing that the level of information required for the submission of an application was disproportionate relative to the level of risk involved.

4.2.7 **Option 7: Enabling the free circulation of nationally authorised products**

4.2.7.16 **Sub-option 7.1: Authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment**

This option would create a single market for established veterinary medicines. Its impact is expected to be significant. It could very quickly address the situation described in Section 2.2.1 whereby a high proportion of veterinary medicinal products are only authorised on a single national market. Market impacts would need to be monitored since this option might expose SMEs to competition from larger companies who were better able to quickly exploit
the opportunities created, though the increased competition would be beneficial in the long-term.

Its effect on product availability is likely to be significant and positive. The range of products available within many product categories would be expected to increase, reducing prices.

Smaller markets are likely to become more attractive propositions once the cost of obtaining an authorisation was removed, and thus smaller countries should experience a significant increase in product availability (though the costs of country-specific packaging and labelling would still act as a disincentive). Consultees and survey respondents from industry were largely supportive of this option.

The administrative burden on industry would decrease substantially as the administrative assessment would replace existing and relatively costly mechanisms for extending MAs to new national markets (e.g. through the MRP). Measuring the scale of the impact is problematic. We have conservatively estimated that were companies able to use an administrative assessment instead of the MRP, then administrative burdens would be reduced by around EUR 14.2 million per year. There is likely to be considerable latent demand for extensions of MAs to additional countries, however, and this option would probably lead to a significant increase in MA applications.

Set against these benefits are the concerns of most regulators as to the impact of this policy option on the protection of human and animal health. There is, at present, a certain lack of trust amongst competent authorities in the quality of assessment carried out by some other authorities, and in the robustness of pharmacovigilance systems, both of which are key to the implementation of this option. These concerns are particularly acute for ‘higher-risk’ products (potentially including antimicrobials and products authorised many years ago).

These concerns could potentially be mitigated by restricting the scope of this policy option to an agreed list of ‘lower-risk’ categories of product and/or restricting eligibility to products authorised during the timeframe of EU veterinary pharmaceutical legislation. It may also be necessary to introduce requirements as to the duration/quality of pharmacovigilance data upon which the record of safe use is based.

4.2.7.17 Sub-option 7.2: Systematically harmonise Summaries of Product Characteristics (SPCs) for authorised products

There was a consensus amongst most consultees and survey respondents that this policy option is, in principle, necessary. Variations in SPCs occur when different outcomes have arisen from different regulators’ interrogation of what is in most cases the same data. They are a barrier to the free movement of goods, and impose administrative burdens on businesses (though it has not been able to measure the scale of this burden).

Whilst the principle behind this policy option was widely supported, there were concerns about the detail. The experiences of the CMDv’s ‘pilot’ programme of voluntary SPC harmonisation should be drawn upon in order to establish the basis for the implementation of this policy option. Key issues include:

- The way in which products are selected for harmonisation (e.g. should this process initially focus on priority products and if so what should they be?); and,

- The composition and funding of the group responsible for carrying out the harmonisation (and if/how companies would be able to input into this process and granted the right to challenge any decision made).

The scale of the task means that the process would take many years and consume considerable resources within regulatory bodies and businesses. The number of referrals that presently occur within the European MA procedures highlight the extent to which authorities still disagree over the interpretation of data, and there is a real danger that the systematic harmonisation of SPCs could suffer from paralysis.

39 The legislative framework dates from 1981 but has been subject to a number of significant amendments, such as in 2001 (Directive 2001/82/EC) and 2004 (Directive 2004/28/EC)
Industry has expressed a concern that harmonisation would lead to the loss of indications from SPCs, particularly for older products where data do not meet current requirements (but which were sufficient at the time of authorisation). Reducing indications could negatively impact on the protection of human and animal health. It would be necessary to establish protocols for such situations. These could potentially draw on pharmacovigilance data. Industry representatives recommended that companies should be able to choose a single ‘reference case’ for the SPC harmonisation, though this would be likely to meet resistance from regulators.

4.2.8 Option 8: Simplifying pharmacovigilance requirements

4.2.8.18 Sub-option 8.1: Abolish pharmacovigilance requirements

This option is not regarded as prudent. Pharmacovigilance data are essential for monitoring the safety of a product once it has been authorised, and there are frequently cases where product SPCs are changed based on how they perform once placed on the market. Consultees and survey respondents, particularly those from regulatory bodies, were almost all opposed to the option. Regulatory bodies warned of significant negative impacts on the protection of human and animal health.

Representatives from industry, whilst supportive of the abolition of a significant administrative burden (savings are estimated to amount to EUR 59.4 million per year), were concerned that a reliance on liability could lead to increased legal costs due to complaints. It was also noted that this option would bring Europe out of line with other VICH markets (the United States and Japan)40.

4.2.8.19 Sub-option 8.2: Simplify pharmacovigilance requirements

This option is popular and viable, though there is further work to be done as regards the details of the proposal. There was a broad consensus amongst consultees and survey respondents from across all stakeholder categories that a simplification of pharmacovigilance requirements is necessary. The current system is based on the system for human medicines, and there is widespread view that the equivalent level of investment is not justified in animal health. With some exceptions, the benefit of collecting pharmacovigilance data for products that had been marketed for decades was seen to be negligible by most consultees.

Industry has argued that the administrative burden associated with meeting pharmacovigilance requirements is prohibitively high (the implementation of this policy option would save an estimated EUR 47.2 million per year). Regulators – particularly those from smaller countries where there may only be a small number of employees – have argued that processing pharmacovigilance submissions consumes too much time and effort.

Whilst supportive of the simplification of pharmacovigilance, regulatory bodies wished to retain the current system for certain categories of product. This included products deemed to be ‘higher-risk’ (e.g. potentially including antimicrobials), and also products based on a new active ingredient.

There is a general belief amongst stakeholders that adverse reactions to medicines are under-reported, particularly by veterinarians. It was suggested that this issue related mainly to the reporting of adverse reactions for older products where such adverse reactions are well known and veterinarians thus did not see the need to provide such information. It was also suggested that there is insufficient detailed feedback from the pharmacovigilance system, which discouraged veterinarians from taking the time to submit information. Overall, therefore, there is a belief amongst many stakeholders that the current pharmacovigilance system is not fit for purpose. A simplification of the system, it was suggested, might encourage improved reporting.

40 VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration, including requirements in relation to pharmacovigilance
4.2.9 Option 9: Simplifying requirements for renewing Marketing Authorisations

4.2.9.20 Sub-option 9.1: Abolish the requirement to renew a MA

This option delivers significant administrative burden savings (an estimated EUR 69.5 million per year) but would involve regulators losing what they see as a useful opportunity to adjust authorisation details.

There was limited support amongst regulators for the complete abolition of MA renewals, as they are seen to provide an opportunity to undertake a much more thorough review of a product post-authorisation than is the case based on a review of pharmacovigilance data. Consultees noted instances where the renewal of a MA had presented an opportunity to have an authorisation changed based on the product’s performance in the market, an amendment that would not have been triggered by pharmacovigilance data alone. Industry, on the other hand, was supportive of the abolition of renewals, which constitute a considerable administrative burden.

4.2.9.21 Sub-option 9.2: Restrict the requirement to renew a MA to specific cases based on the risk profile of the product

This option is, for regulators, a more palatable option because requires a renewal procedure for higher-risk products and still delivers significant administrative burden savings to industry. An EU-wide framework for the determination of the risk profile of products would be required to ensure consistency. This could potentially be the same framework used to support other sub-options, such as Options 4 and 7).

Regulators were, for the most part, more supportive of the restriction in the use of renewals than they were of their complete abolition. Industry was enthusiastic about the potential reduction in the administrative burden that would result from this policy option (annual savings could be worth up to EUR 67.5 million, assuming that the majority of products – industry representatives believed the figure to be 95 per cent of products – would be classed as lower-risk), but expressed concerns about how it would be implemented. Specifically, it was noted that the renewal requirement should be applied (or not applied) consistently, rather than one country requiring a renewal and another not (though regulators noted that the risk profile of a product might change between countries).

4.2.10 Option 10: Simplifying data recording and reporting requirements

4.2.10.22 Sub-option 10.1: The amount of data that must be recorded and reported is reduced

Without additional detail on the identity of the data recording and reporting requirements that would be reduced, stakeholders were unable to comment on the proposal. It was assumed by most survey respondents that this policy option would reduce the scale of the administrative burden (though this decrease could not be measured).

It can be assumed that this policy option will apply to the veterinary medicine supply chain, since reductions in data requirements as part of the product authorisation process form part of other policy options. Only veterinarians were included within the consultation exercise carried out for this study, and consultees and survey respondents did not believe that there were any significant unnecessary data recording and reporting requirements at present.

4.2.11 Option 11: Simplifying packaging and labelling requirements

4.2.11.23 Sub-option 11.1: Prior approval of packaging and labelling by the authorities is abolished

There was a clear divide as regards this policy option, with representatives from industry largely in favour of its implementation, and representatives from regulatory bodies largely against its introduction. From an industry perspective it was felt that prior approval of packaging and labelling generates an administrative burden (though it has not been possible to quantify the scale of this burden) and imposes delays, and provides competent authorities with an opportunity to impose country-specific packaging and labelling requirements.

Regulators, conversely, stressed that prior approval of packaging and labelling provides an opportunity to ensure compliance with the legislation before products are placed on the
Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

market and thus help to protect human and animal health. Regulators cited frequent instances of non-compliance, and stated that without prior approval these products would have had to be recalled from the market at considerable cost to industry (though in practice the financial cost of such recalls, together with the impact on a company’s reputation, would presumably mean that MA holders would be more careful about compliance). Regulators also noted that the scale of in-market checks would need to be increased significantly in order to ensure compliance.

Consultations with Member States indicates that some countries – particularly smaller Member States – waive the requirement for prior approval of packaging and labelling since they do not have the resources to carry out such assessments.

4.2.11.24 Sub-option 11.2: The amount of text required on packaging and labelling is reduced

This option is popular in principle but the challenge lies in finding ways to achieve the reduction in text while satisfying concerns about clarity and interpretation and provision of complementary sources of information.

Representatives from industry were in favour of this policy option, noting that reductions in packaging and labelling text would result in a significant decrease in administrative burdens (though it has not been possible to quantify the scale of this burden), and would make it feasible to market products in smaller countries, thus increasing availability. Regulators were also generally in favour of this policy option, with the proviso that reductions in text did not compromise the protection of health. For this reason it was stressed that the information contained in leaflets should not be reduced, and that any abbreviations and pictograms that were used would need to be carefully designed and agreed throughout the EU/EEA.

Consultees from end user groups were also in favour of reductions in packaging and labelling text since this would increase the availability of medicines. However, it was also suggested that any reductions in the text contained on/in individual products should be counterbalanced by improvements in alternative sources of information, such as drug compendia and/or product barcodes.

4.2.11.25 Sub-option 11.3: Authorities may authorise the use of non-official languages

This option provides national authorities with the option of allowing marketing of products labelled in languages other than their Member State’s official languages. It could help improve the economics of serving small markets but authorities would need to assess the potential risks of non-expert end users not being able to understand the label.

Industry representatives suggested that this policy option would decrease administrative burdens (though it has not been possible to quantify the scale of this burden) and make it feasible to market products within smaller countries, since packaging and labelling could be produced in one of the major EU languages, removing the need for small batches.

Whilst generally agreeing with the need for this policy option, regulators expressed some concern that this policy option might affect the protection of human and animal health, due to a risk that packaging and labelling instructions might not be understood by non-expert end users (i.e. not veterinarians) who were unable to speak non-native languages. There may also be legal problems where products are not produced in native languages.

4.2.12 Option 12: Simplifying requirements for applying for variations to MAs

4.2.12.26 Sub-option 12.1: Simplifying variations requirements

With further development, this option could deliver savings in administrative burdens. Further work would be needed on how to simplify current arrangements whilst ensuring that competent authorities are notified of administrative adjustments to the MA.

Whilst supportive of the goal to reduce administrative burdens, consultees and survey respondents from regulatory bodies raised concerns about the impacts that this policy option could have on the protection of human and animal health. Their expectation was that the authorities should always be informed of any changes to a MA, and that this requirement should be retained even if MA holders were permitted to actually make the changes.
themselves. Increased usage of electronic communication methods could enable MA holders to keep competent authorities informed of any changes without recourse to the submission of paper versions of variations.

Businesses were in favour of this policy option, noting that it would reduce administrative burdens in an area that they do not feel contributes significantly to the protection of health.

The savings to the administrative burden incurred by industry is estimated to be around EUR 10.9 million per year, but the exact value of the reduction will depend on which types of variation are included within the simplification exercise (for the development of the SCM we have assumed that it applies only to Type 1A variations).

4.2.13 Option 13: Amending the scope of the cascade

4.2.13.27 Sub-option 13.1: Abolish the cascade

There was no support for this policy option amongst consultees or survey respondents. End user groups expressed particular concern that this option would have a highly detrimental impact on animal welfare, and would encourage the illegal and unregulated usage of veterinary and human medicinal products. Veterinarians argued that the cascade will always be a key provision in the treatment of animals, since there will never be universal availability of medicines.

Representatives from industry, who might, potentially, benefit from a removal of the cascade (the over- and illegal use of which might act as a disincentive to invest in new medicines), were not supportive of this option due to animal welfare concerns. They noted that regulatory costs are a more significant disincentive for investment than the usage of the cascade.

4.2.13.28 Sub-option 13.2: Reduce the scope of the cascade

Whilst the way in which usage of the cascade would be restricted was not defined, there was some support amongst consultees for reordering the order of the cascade, such that the usage of human medicines become the last possible option. It was noted, however, that this would present practical problems, and it may be necessary to caveat this reordering such that in cases where immediate treatment is needed, human medicines could be used before medicines authorised in other countries.

There was little support for this policy option from the industry, despite the fact that the over- and illegal use of the cascade could potentially act as a disincentive for the development of new medicines. Other factors were seen as more important when seeking to remove barriers to investment.

Many stakeholders argued that the cascade is already sufficiently restrictive, and that the suspected problem of overuse was a result of insufficient enforcement, which would not be solved by the introduction into the legislation of further reductions in scope.

4.2.13.29 Sub-option 13.3: Increase the scope of the cascade

This option divided opinion. End user groups were largely in favour, mainly because extending the scope of the cascade would increase the range of medicines that veterinarians could use to treat animals. Specifically, end user groups argued that a relaxation of the cascade is needed for companion animals, since the risk to human health is lower. This need was seen to be particularly acute for minor species, where there are very few authorised medicines available. Proposed measures included allowing the cascade to be used for reasons other than a lack of availability of medicines (e.g. the use of human medicines because they tend to be cheaper), and permitting the importation and usage of medicines from third countries.

Representatives from industry and regulatory bodies, however, were largely against this policy option. Industry consultees and survey respondents suggested that relaxing the cascade would effectively permit veterinarians to bypass the authorisation system, and would act as a strong disincentive for the development of new medicines and the extension of existing authorisations to new species and markets.
Representatives from regulatory bodies stressed the potential risk to human and animal health of a relaxation of the cascade, even if this were restricted to companion animals (for example when they come into contact with humans). There was particular concern about the usage of human medicines within animals, in part for animal welfare reasons (e.g. due to problems calculating dosages), but also due to fears that this would encourage the unchecked usage of critical human antimicrobials.

4.2.14 Option 14: Amending data protection to reward new product development

There are 10 sub-options within Option 14. Each is covered separately in the analysis below. Most of the options above facilitate the ‘dissemination’ of existing products across the EU, and/or lower the costs of keeping existing products on the market. Some sub-options of Option 14 affect the economics of investment in new products and thus, potentially, the rate of innovation in the market. They also create winners and losers within the industry, having differing impacts on manufacturers of generic and innovative products. Other elements of Option 14 encourage the distribution of products across more species.

4.2.14.30 Sub-option 14.1: The maximum period of data protection is extended to 16 years

The suitability of the 16 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development. Views within the industry, predictably, differed between producers of generics and those developing novel products.

Developers of novel products were supportive of the option, noting that the extension of the data protection period would increase the return on investment that could be achieved, and would thus make more marginal markets (e.g. minor species) more attractive (although the option as currently stated does not focus extended data protection periods on specific areas of need, e.g. minor species).

Conversely, representatives of developers of generics products expressed concern that an extension of the data protection period would delay the entrance of generics products onto the market and affect the viability of the sector. Consultees noted that developers of novel products would receive 16 years of data protection even within profitable markets.

The treatment of extensions to MAs under this policy option would need to be determined.

4.2.14.31 Sub-option 14.2: The maximum period of data protection is extended to 20 years

The suitability of the 20 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development.

Unsurprisingly, stakeholders from developers of novel products were supportive of this policy option. They noted that the extension of the data protection period would increase the return on investment that could be achieved. It was claimed that more marginal markets (e.g. minor species) would be more attractive (though others have disputed whether capital would in practice be allocated to smaller markets).

Conversely, representatives of developers of generics products expressed concern that an extension of the data protection period would delay the entrance of generics products onto the market and affect the viability of the sector. Consultees noted that developers of novel products would receive 20 years of data protection even within profitable markets.

The treatment of extensions to MAs under this policy option would need to be determined.

4.2.14.32 Sub-option 14.3: An extra 3 years of protection is added for each extension to a MA, up to a maximum of 20 years

This option could encourage the authorisation and marketing of individual products for more species, if it is carefully specified.
Consultees from industry were generally supportive of this option, which would increase the data protection period for each species added to a MA from 1 to 3 years. It was, however, suggested that this change would probably make the addition of major species to a MA a more attractive proposition, but would have little impact on the return on investment generated by adding a minor species.

Regulators and developers of generics products raised a concern that the definition of an ‘extension’ to an MA should be carefully considered, and should be restricted to major developments (such as a new species). This proposal is contained in a separate policy option (see Option 14.4). It was suggested that unless this caveat was introduced, developers of novel medicines might repeatedly introduce minor extensions in order to protect themselves from competition from generics products, with an associated negative impact on the range of medicines available and the prices paid by end users.

The suitability of the 20 years maximum period of data protection is difficult to assess. In practice for some species / indications this will probably be too long, and in others too short to justify investment in product development.

4.2.14.33 Sub-option 14.4: An extra 3 years of protection is added for each ‘major’ extension, and an extra 1 year is added for each ‘minor’ extension, up to a maximum of 20 years

As for Option 14.3, consultees from developers of novel medicines were supportive of an extension of the data protection period for each species added to a MA from 1 to 3 years, indicating that this would increase the return on investment. Regulators and developers of generics products were also in favour of the introduction of a distinction between major and minor extensions, noting that this would prevent companies from using MA extensions to protect themselves from competition from generics products.

Many consultees were concerned about how the proposed committee would operate, how it would be funded, and what impact it would have on the time taken to assess MA applications.

The suitability of the 20 years maximum period of data protection is difficult to assess. In practice for some species/ indications this will probably be too long, and in others too short to justify investment in product development.

4.2.14.34 Sub-option 14.5: Rewards for new product developments are decoupled from the initial authorisation

For industry this was the most popular of the options relating to data protection. The current 5 year ‘limit’ on the introduction of extensions was considered not to fit with the reality of how products are tested on the market for a period of time before decisions are made as to whether to invest in extensions to new species. It was suggested that the removal of this limit would have a significant impact on the availability of medicines, a proposition that was not opposed by representatives of generics producers.

As it stands, this policy option would also apply any product with a MA, and thus authorisations granted many years ago could be extended to new species, with data protection. Again, industry representatives suggested that this could be a significant incentive to invest in innovation.

4.2.14.35 Sub-option 14.6: The data protection period for environmental risks is changed to match that for safety and efficacy data

Consultees and survey respondents were largely in favour of this policy option, noting that the current treatment of environmental risk information is inconsistent when compared with other data. This policy option would correct this inconsistency and reduce the costs of obtaining an authorisation for a generic product, thus potentially increasing the number of such products on the market.

Representatives from companies involved in the development of novel products claimed that this option would have a negative impact on the return on investment generated from new product development (since they currently benefit from unlimited data protection, thus
increasing the cost of submitting an application for a generic product) and consequently did not want it to be implemented in isolation.

4.2.14.36 Sub-option 14.7: The period of data protection for fish, bees and other specific species/indications is extended to 16 years

Representatives from developers of novel products were supportive of any extension to the data protection period, noting that this would increase the return on investment, and thus make these areas more attractive. Producers of generic products, conversely, raised concerns that extensions to the data protection period prevent the entry of generics into the market, thus decreasing competition.

The suitability of the 16 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development.

Several stakeholders noted that fish and bees already benefit from extended data protection, and yet there remain problems with the availability of medicines, and thus that this policy option would in all likelihood not affect them. These markets are fundamentally small, and thus struggle to attract investment.

It was suggested, however, that this option could have an impact depending on the definition of ‘other specific species/indications’. The development of new medicines to serve certain minor species is simpler (e.g. where they are similar to major species – e.g. cattle and goats), and an extension to the data protection period in such cases could make a significant difference.

4.2.14.37 Sub-option 14.8: The period of data protection for fish, bees and other specific species/indications is extended to 20 years

Representatives from developers of novel products were supportive of any extension to the data protection period, noting that this would increase the return on investment, and thus make these areas more attractive. Producers of generic products, conversely, raised concerns that extensions to the data protection period prevent the entry of generics into the market, thus decreasing competition.

The suitability of the 20 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development.

As with Option 14.7 the impact of this sub-option was doubted by several stakeholders who noted that fish and bees already benefit from extended data protection, and yet there remain problems with the availability of medicines. As with Option 14.7, this option could have an impact depending on the definition of ‘other specific species/indications’ in encouraging extension from major species (e.g. cattle and goats) to related minor species.

4.2.14.38 Sub-option 14.9: MA extensions for small markets are rewarded with an extra 2 years of protection, up to 16 years

This policy option needs to be better defined before the impact can be assessed, specifically what ‘small markets’ will include.

The consensus amongst consultees and survey respondents from industry, where they felt able to comment, was that this policy option would have less of an impact than most of the other proposals for changing data protection. Two additional years of data protection was not considered sufficiently attractive to justify investing in extending a MA to a small market;

The suitability of the 16 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development.
4.2.14.39 Sub-option 14.10: MA extensions for small markets are rewarded with an extra 2 years of protection, up to 20 years

This policy option needs to be better defined before the impact can be assessed, specifically what 'small markets' will include.

As with Option 14.9, consultees and survey respondents from industry who commented suggested that this policy option would have less of an impact than most of the other proposals for changing data protection. Two additional years of data protection was not considered sufficiently attractive to justify investing in extending a MA to a small market.

As with the other cases, the suitability of the 20 years maximum period of data protection is difficult to assess.

4.2.15 Option 15: Introducing support for SMEs

4.2.15.40 Sub-option 15.1: Introducing support for SMEs

Consultees reported that this option might have a slight impact on the availability of medicines, primarily by increasing the success rate of SMEs when applying for new MAs. There are issues for national competent authorities in implementing this option, since they will need to generate resources from elsewhere to fill the gaps resulting from reduced income from SMEs. In some countries cross-subsidisation of one group of businesses through higher charges to another is not allowed. A tight public spending environment puts pressure on use of finance raised from taxpayers.

4.2.16 Option 16: Clarifying the scope of the legislation with regard to new treatments

4.2.16.41 Sub-option 16.1: Clarifying the scope of the legislation with regard to new treatment types

There was widespread support for this policy option, which it was felt would introduce harmonisation where there is presently divergence between national approaches. This would have a positive impact on the operation of the single market.

Stakeholders noted that legislating effectively within fast-changing and high technology areas is difficult, and that the legislation should be flexible enough to ensure that the definitions used do not hinder innovation. Furthermore, harmonisation with other major markets is as important as harmonisation within the EU/EEA.

4.2.17 Option 17: Addressing the problem of potential antimicrobial resistance

4.2.17.42 Sub-option 17.1: Critical antimicrobials for human use are prohibited for use in the veterinary sector

There was very little support for this policy option amongst consultees and survey respondents. Representatives from end user groups in particular were strongly against any restriction in the range of products that veterinarians can use to treat animals. There were claims that the banning of a significant group of antimicrobial products would have serious consequences for animal health. Some respondents suggested that if the law were followed, veterinarians would have to resort to euthanasia, and illegal and unchecked usage of critical human antimicrobials would increase.

Many consultees challenged the science underpinning the assumption that banning the usage of critical human antimicrobial medicines within animals would have an impact on the development of antimicrobial resistance.

Some countries already restrict the usage of critical antimicrobials without enforcing a universal ban.

4.2.17.43 Sub-option 17.2: Potential impacts on antimicrobial resistance are addressed as part of the MA process

Antimicrobial resistance is already included in the assessment process (see Section 3.2.18), and so the additional impact of this policy option would be limited. There was, however, a consensus amongst regulators and end users that this policy option would have a positive
impact on the protection of health, provided the requirements also applied to generics, and the assessment of resistance included consideration of usage under the cascade.

4.2.17.44 Sub-option 17.3: Veterinarians are prohibited from selling antimicrobials

There was little support for this policy option amongst consultees and survey respondents. Representatives from end user groups suggested that restrictions on the operations of veterinary practices would have a serious impact on their viability, and would lead to practice closures.

Consultees from end user groups questioned whether this policy option would have any effect on tackling antimicrobial resistance, claiming that there was no empirical evidence available that veterinarians are over-prescribing antimicrobials simply to generate additional income.

Consultees and survey respondents suggested that it would have a significant negative impact on animal health, since situations would arise – particularly in rural areas – where veterinarians needed to be able to distribute antimicrobials immediately, but could not. They claimed there is a danger that this would stimulate the illegal trade and usage of antimicrobials which, since it would be unregulated and unmonitored by veterinarians, would pose risks to human and animal health.

This policy option would generate a cost to industry. SPCs and product packaging and labelling would need to be revised for all authorised antimicrobials in order to reflect the changes to their method of distribution.

4.2.17.45 Sub-option 17.4: A system is established for collecting data on the sales and usage of antimicrobials

Elements of this policy option already exist to varying degrees, (particularly for food-producing species), and so the basis for such a system is in place to build upon. Stakeholders were almost unanimously in favour of this proposal, provided it is implemented effectively and does not create an excessive administrative burden on businesses and veterinarians.

4.2.17.46 Sub-option 17.5: Controls on the advertising and marketing of antimicrobials to veterinarians

Consultees and survey respondents expressed concerns about the workability of this proposal, particularly the enforcement by the authorities. Representatives from both end user groups and industry argued that advertising and marketing is a crucial means of communicating information on product developments, and ensures that veterinarians are fully informed about the correct usage of antimicrobials. There was little support for an outright ban on advertising and marketing, though it was suggested that other approaches – e.g. restrictions on the information that can be promoted (e.g. withdrawal periods) and/or a code of practice – might be beneficial.

Representatives from all stakeholder groups suggested that the advertising and marketing of antimicrobials to end users (farmers and companion animal owners) was more problematic since this led to pressure being applied to veterinarians. In most countries the advertising and marketing of antimicrobials to ‘laypersons’ is banned or restricted, but interpretations of laypersons vary between countries, and there may be a need for further harmonisation or control measures.

4.2.18 Option 18: Improving harmonisation and oversight of in-market control

4.2.18.47 Sub-option 18.1: National control systems are required to meet agreed European standards, and the Commission has the powers to check such systems

Consultees were in principle supportive of greater harmonisation of control systems, noting that this would have a positive impact on the operation of the single market and on the protection of human and animal health. However, most requested further detail on the content of the control system standards, and did not feel able to draw conclusions on this policy option until such information was made available.
4.2.18.48 Sub-option 18.2: Harmonised EU sanctions are introduced for non-compliance

Consultees were in principle supportive of the harmonisation of sanctions across the EU/EEA, noting that this would have a positive impact on the operation of the single market and on the protection of human and animal health. However, it was noted that sanctions already exist across the EU/EEA, and thus that this policy option would not have a significant impact on non-compliance.

4.2.19 Option 19: Enforcing a European database of authorised products

4.2.19.49 Sub-option 19.1: Enforcing a European database of authorised products

A database of authorised products was supported by most consultees and survey respondents, who noted that it would provide a valuable resource that could be used by industry, regulators and veterinarians alike. The major benefit of the database would be to improve transparency within the authorisation system. Veterinarians would be able to see which products were available where, information that could be valuable if medicines were unavailable (with implications for the operation of the cascade). It was also suggested that the database would highlight inconsistencies between countries, for instance variations in SPCs for the same product.

To work effectively though the database would need to be underpinned by harmonised reporting protocols, to ensure that the information submitted by the competent authorities was consistent. The database would also need to be regularly updated if it was not to become a historical record of authorisations. Ensuring that stakeholders were aware of how often the database was updated would ensure confidence in the data contained within.

4.3 Synthesis of the results of the impact assessment

This section of the report has presented the results of the assessment of the impacts of each of the policy options for the proposed revision to the legislative framework for veterinary medicinal products. Four impact assessment criteria have been considered, consisting of an assessment of the impact of the policy options on: the availability of medicines; the protection of human and animal health; the operation of the single market; and the administrative burdens imposed on stakeholders. In addition to measuring impacts, we have also sought to summarise the opinions of stakeholders on the implementation of each policy option. This has included an assessment of potential implementation challenges, and also the identification of possible mitigation strategies through which policy options could be amended in order to address any issues with their implementation.

Table 4.23 presents a synthesis of the results of the impact assessment. For each policy option we present:

- A summary ‘score’ of the impact of the proposals on the availability of medicines, the protection of human and animal health, and the operation of the single market. These scores consist of the study team’s synthesis of the views of stakeholders together with our own assessment of the likely impact of each policy option, based on the evidence reviewed previously;

- The value of the administrative burden on industry saved/ created by the policy options, if relevant. Where the burden cannot be measured a qualitative assessment of the direction of change is indicated. Where policy options will have a notable impact on the administrative burden imposed on regulators, this is also identified;

- A summary of the challenges associated with the implementation of the policy options (if any). Again this summary is a synthesis of the views of stakeholders and the study team’s assessment, based on the available evidence;

- Identification of mitigation strategies that could overcome challenges with the implementation of the policy options (if any).
### Table 4.23 Synthesis of the principle results of the impact assessment

<table>
<thead>
<tr>
<th>Ref</th>
<th>Policy option</th>
<th>Ref</th>
<th>Sub-option</th>
<th>Impact on Free movement</th>
<th>Impact on Medicine availability</th>
<th>Impact on Health protection</th>
<th>Estimated impact on admin burdens (€m p.a.)</th>
<th>Implementation challenges</th>
<th>Possible mitigation strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Extending the scope of the Centralised Procedure</td>
<td>1.1</td>
<td>The CP becomes mandatory for all products</td>
<td>+</td>
<td>-</td>
<td>o</td>
<td>+170.8</td>
<td>Capacity of EMA to process all applications</td>
<td>Change EMA procedures to allow decentralisation of some decision-making to national authorities</td>
</tr>
<tr>
<td>1.2</td>
<td>Extending the scope of the Centralised Procedure</td>
<td>1.2</td>
<td>The CP becomes mandatory for all products with new active substances</td>
<td>o</td>
<td>o</td>
<td>o</td>
<td>0</td>
<td>None</td>
<td>Not relevant</td>
</tr>
<tr>
<td>1.3</td>
<td>Extending the scope of the Centralised Procedure</td>
<td>1.3</td>
<td>The CP is made available for all products</td>
<td>+</td>
<td>+</td>
<td>o</td>
<td>-5.6</td>
<td>Capacity of EMA to process a significant increase in applications</td>
<td>Change EMA procedures to allow decentralisation of some decision-making to national authorities</td>
</tr>
<tr>
<td>1.4</td>
<td>Extending the scope of the Centralised Procedure</td>
<td>1.4</td>
<td>The CP becomes mandatory for all products requiring specific expertise, and is made available for all products</td>
<td>+</td>
<td>+</td>
<td>o</td>
<td>-5.6</td>
<td>Capacity of EMA to process a significant increase in applications</td>
<td>Change EMA procedures to allow decentralisation of some decision-making to national authorities</td>
</tr>
<tr>
<td>2.1</td>
<td>Making a single Marketing Authorisation valid throughout the EU/EEA</td>
<td>2.1</td>
<td>The quality of the work of the competent authorities would be ensured by an independent EU body</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-67.9</td>
<td>Lack of trust amongst national authorities</td>
<td>Assessments could be peer reviewed by a second competent authority</td>
</tr>
<tr>
<td>2.2</td>
<td>Making a single Marketing Authorisation valid throughout the EU/EEA</td>
<td>2.2</td>
<td>The quality of the work of the competent authorities</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-67.9</td>
<td>Lack of trust amongst national authorities</td>
<td>Assessments could be peer reviewed by a second competent authority</td>
</tr>
</tbody>
</table>
## Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

### Impact:
- **+ +** means significant positive impact
- **o** means neutral impact
- **– –** means significant negative impact

### Estimated impact on admin burhden (€m p.a.)

<table>
<thead>
<tr>
<th>Ref</th>
<th>Policy option</th>
<th>Sub-option</th>
<th>Impact</th>
<th>Implementation challenges</th>
<th>Possible mitigation strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Improving the operation of current authorisation procedures</td>
<td>3.1 Voluntary recognition of MAs on a case-by-case basis by competent authorities</td>
<td>Free movement: o</td>
<td>Lack of trust amongst national authorities</td>
<td>Assessments could be peer reviewed by another competent authority</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Medicine availability: o</td>
<td>Transparency of decision-making</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Health protection: o</td>
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<td>Funding and powers of the national accreditation system</td>
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<td></td>
<td>Initially restrict to low-risk products</td>
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<tr>
<td></td>
<td></td>
<td>3.2 Automatic recognition of MAs by competent authorities</td>
<td>Free movement: +</td>
<td>Lack of trust amongst national authorities</td>
<td>Assessments could be peer reviewed by another competent authority</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Medicine availability: +</td>
<td>Transparency of decision-making</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Health protection: o</td>
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<td></td>
<td></td>
<td>3.3 Improved coordination between competent authorities</td>
<td>Free movement: o</td>
<td>Lack of trust amongst national authorities</td>
<td>Assessments could be peer reviewed by another competent authority</td>
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<td></td>
<td></td>
<td></td>
<td>Medicine availability: o</td>
<td>Transparency of decision-making</td>
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<td></td>
<td></td>
<td></td>
<td>Health protection: o</td>
<td></td>
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<tr>
<td>4</td>
<td>Simplifying the Marketing Authorisation process for low-risk and generic products</td>
<td>4.1 For low-risk/ generic products a fast-track system of authorisation is introduced</td>
<td>Free movement: +</td>
<td>Lack of trust as regards thoroughness of fast-track assessments</td>
<td>Assessments could be peer reviewed by another competent authority</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Medicine availability: +</td>
<td>Definition of low-risk</td>
<td>Standardised EU framework for classifying low-risk products</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Health protection: –</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.2 For low-risk/ generic products a system of</td>
<td>Free movement: +</td>
<td>Lack of trust in historical</td>
<td>Standardised EU framework for</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Medicine availability: +</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Health protection: –</td>
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</tbody>
</table>
### Impact of the Revision of Veterinary Pharmaceutical Legislation

<table>
<thead>
<tr>
<th>Ref</th>
<th>Policy option</th>
<th>Sub-option</th>
<th>Impact: Free movement</th>
<th>Medicine availability</th>
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</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Reducing data requirements for authorisations</td>
<td>5.1 Data requirements for product authorisations are reduced</td>
<td>o</td>
<td>+</td>
<td>– if safety data</td>
<td>Decrease</td>
<td>Resistance from regulators to reduced safety data</td>
<td>Initially restrict to low-risk products</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.2 Under certain circumstances products are granted authorisations</td>
<td>+</td>
<td>+</td>
<td>++</td>
<td>Decrease</td>
<td>None</td>
<td>Not relevant</td>
</tr>
<tr>
<td>6</td>
<td>Simplifying requirements for homeopathic products</td>
<td>6.1 Homeopathic products are excluded from the scope of the legislation</td>
<td>+ (homeo. medicines)</td>
<td>+ (homeo. medicines)</td>
<td>?</td>
<td>Decrease</td>
<td>Widely supported principle that all medicinal claims should be supported by evidence</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6.2 The registration procedure for homeopathic products is simplified</td>
<td>+ (homeo. medicines)</td>
<td>+ (homeo. medicines)</td>
<td>?</td>
<td>Decrease</td>
<td>Widely supported principle that all medicinal claims should be supported by evidence</td>
<td>None</td>
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<tr>
<td>7</td>
<td>Enabling the free circulation of authorised products</td>
<td>7.1 Authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment</td>
<td>+ +</td>
<td>+ +</td>
<td>o</td>
<td>-14.2</td>
<td>Definition of safe use</td>
<td>Restrict to authorisations since 2001/2004, or perhaps since 1981</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.2 Systematically harmonise</td>
<td>+ +</td>
<td>+ +</td>
<td>o</td>
<td>Decrease for Cost of harmonisation</td>
<td>Focus on priority</td>
<td></td>
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<tr>
<td>Ref</td>
<td>Policy option</td>
<td>Sub-option</td>
<td>Impact:</td>
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<td>+ + means significant positive</td>
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<td>o means neutral</td>
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<td></td>
<td>– – means significant negative</td>
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<td>o</td>
<td>– –</td>
<td>-59.4</td>
<td>Significant resistance from regulators</td>
<td>Restrict to low-risk products</td>
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<td>o</td>
<td>o</td>
<td>o</td>
<td>-47.2</td>
<td>Resistance from regulators for high-risk products</td>
<td>Restrict to low-risk products</td>
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<td>9.1 Abolish the requirement to renew a MA</td>
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<td>o</td>
<td>–</td>
<td>-69.5</td>
<td>Significant resistance from regulators</td>
<td>Restrict to low-risk products</td>
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<td></td>
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<td>9.2 Restrict the requirement to renew a MA to specific cases based on the risk profile of the product</td>
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<td>o</td>
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<td>Resistance from regulators for high-risk products</td>
<td>Restrict to low-risk products</td>
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<td>– if safety data</td>
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<td>Lack of detail about data to be included</td>
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<td>o</td>
<td>Decrease</td>
<td>Some resistance from regulators</td>
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<td>Resourcing of increased in-market control</td>
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<td>Pan-EU strategy for in-market control standards</td>
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<td></td>
<td>11.2 The amount of text required</td>
<td>+ +</td>
<td>+ +</td>
<td>o</td>
<td>Decrease</td>
<td>Design of pictograms, Restrict to products</td>
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## Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

<table>
<thead>
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<td>Free movement</td>
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<td>The authorities may authorise the use of non-official languages</td>
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<td>+</td>
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<td>13</td>
<td>Amending the scope of the cascade</td>
<td>13.1</td>
<td>Abolish the cascade</td>
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<td></td>
<td>13.2</td>
<td>Reduce the scope of the cascade</td>
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<td>13.3</td>
<td>Increase the scope of the cascade</td>
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<td>Amending data protection to better reward new product developments</td>
<td>14.1</td>
<td>The maximum period of data protection is extended to 16 years</td>
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<tr>
<td></td>
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<td>14.2</td>
<td>The maximum period of data protection is extended</td>
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<td>Ref</td>
<td>Policy option particularly for MUMS uses</td>
<td>Ref</td>
<td>Sub-option</td>
<td>Impact: Free movement</td>
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<td>----------------------------------------------------------------------------</td>
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<tr>
<td></td>
<td></td>
<td>14.3</td>
<td>An extra 3 years of protection is added for each extension to a MA, up to a maximum of 20 years</td>
<td>o</td>
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<tr>
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<td></td>
<td>14.4</td>
<td>An extra 3 years of protection is added for each 'major' extension, and an extra 1 year is added for each 'minor' extension, up to a maximum of 20 years</td>
<td>o</td>
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<td>14.5</td>
<td>Rewards for new product developments are decoupled from the initial authorisation</td>
<td>o</td>
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<td></td>
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<td>14.6</td>
<td>The data protection period for environmental risks is changed to match that for safety and efficacy data</td>
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<td></td>
<td></td>
<td>14.7</td>
<td>The period of data protection for fish, bees and other specific species/indications is extended to 16 years</td>
<td>o</td>
</tr>
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<td>14.8</td>
<td>The period of data protection for fish, bees and other specific species/indications is extended to 20 years</td>
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### Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

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<td>+ + means significant positive</td>
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<td>– – means significant negative</td>
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</tbody>
</table>

| Estimated | Implementation | Possible mitigation |
| impact on | challenges     | strategies          |
| admin      |                |                    |
| burdens    |                |                    |
| (€m p.a.)  |                |                    |

<table>
<thead>
<tr>
<th>Free</th>
<th>Medicine availability</th>
<th>Health protection</th>
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<tr>
<td>movement</td>
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### Free movement

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<th>Implementation challenges</th>
<th>Possible mitigation strategies</th>
</tr>
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<tbody>
<tr>
<td>o</td>
<td>+</td>
<td>o</td>
<td>0</td>
<td>None</td>
<td>Not relevant</td>
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<td>14.9 Ref</td>
<td>MA extensions for small markets are rewarded with an extra 2 years of protection, up to 16 years</td>
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<td>Introducing support for SMEs</td>
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<td>15.1 Ref</td>
<td>Introducing support for SMEs</td>
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<td>Clarifying the scope of the legislation with regard to new types of treatment</td>
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<td>Addressing the problem of antimicrobial resistance</td>
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<td>17.1 Ref</td>
<td>Critical antimicrobials for human use are prohibited for use in the veterinary sector</td>
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<td>17.2 Ref</td>
<td>Potential impacts on antimicrobial resistance are addressed as part of the MA process</td>
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<tr>
<td>17.3 Ref</td>
<td>Veterinarians are prohibited from selling antimicrobials</td>
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### Implementation challenges

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<th>Possible mitigation strategies</th>
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### Possible mitigation strategies

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**Final Report**
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<tr>
<td>17.4</td>
<td>A system is established for collecting data on the sales and usage of antimicrobials</td>
<td></td>
<td>o</td>
<td>o</td>
<td>+</td>
<td>Increase</td>
<td>None</td>
<td>Not relevant</td>
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<td>17.5</td>
<td>Controls on the advertising and marketing of antimicrobials to veterinarians</td>
<td></td>
<td>o</td>
<td>o</td>
<td>?</td>
<td>0</td>
<td>Resistance from veterinarians and industry</td>
<td>None</td>
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<tr>
<td>18</td>
<td>Improving harmonisation and oversight of in-market control systems</td>
<td>National control systems are required to meet agreed European standards, and the Commission has the powers to check such systems</td>
<td>+</td>
<td>o</td>
<td>+</td>
<td>Increase for authorities</td>
<td>None</td>
<td>Not relevant</td>
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<td>18.2</td>
<td>Harmonised EU sanctions are introduced for non-compliance</td>
<td></td>
<td>+</td>
<td>o</td>
<td>+</td>
<td>0</td>
<td>None</td>
<td>Not relevant</td>
</tr>
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<td>19</td>
<td>Enforcing a European database of authorised products</td>
<td>Enforcing a European database of authorised products</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>Increase for authorities</td>
<td>Keeping database up-to-date</td>
<td>Reporting protocols</td>
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Impact: 
+ + means significant positive
o     means neutral
– – means significant negative

Implementation challenges:
- Impact on animal health in rural areas
- Applicability in countries where only veterinarians can sell animal medicines

Possible mitigation strategies:
- Quantities of medicines for immediate usage
- Reporting protocols
- Circulation of information about who has provided up-to-date data
5 Conclusions and Recommendations

This final section of the report presents the conclusions and recommendations of the study team.

A synthesis 'package' of policy options is presented, drawing on the results of the impact assessment. This package of measures has the potential to make a significant difference to the problems that face the sector – reducing administrative burdens and encouraging more products to be made available without sacrificing standards of human or animal health protection.

Whilst there are areas where further work will be needed in order to reach a consensus amongst the different stakeholder groups, there is a considerable appetite for change throughout the sector. The option assessment shows that there is common ground that can provide a foundation for the proposed reforms.

This section of the report firstly considers how policy options can be combined into ‘packages’ of measures depending on which policy goals are prioritised. Utilising the results of this exercise a synthesis package of measures is then identified. The report then provides a commentary on how this package could be implemented.

Some options omitted from the synthesis package have potential to effect positive change but need further work to enhance potential benefits or reduce potential risks. These areas where further consideration and development are warranted are reviewed.

The section finishes with a proposed set of monitoring and evaluation indicators that could be used to assess the effectiveness of this synthesis package.

5.1 Developing ‘packages’ of policy options

The analysis presented in the preceding section of the report analysed each of the 49 policy options independently. These policy options need to be combined into a ‘package’ of measures, since they each address specific aspects of the ‘problem’, and would on their own be insufficient. Many policy options are mutually exclusive – providing alternative means of addressing a particular issue (e.g. the policy options relating to revisions to the MA system). In other cases there is one proposal which addresses a specific issue, without any alternatives (other than to do nothing). The policy option relating to a European database of authorised products is one example.

The impact assessment presented in Section 4 and Annex 12 appraised the policy options against four criteria, based on the high level general objectives for the legislative revision that were set out in Section 3.1. To recap, these general objectives were as follows:

- To improve the functioning of the single market in veterinary medicinal products;
- To enhance the level of protection for humans, animals and the environment, by:
  - Increasing the availability of veterinary medicinal products;
  - Ensuring that all proposals protect the health of humans and animals;
- To reduce the administrative burden imposed on businesses.

As the analysis presented in Section 4 and Annex 12 made clear, options’ performance against the each of the four impact assessment criteria could vary considerably. A policy option might reduce administrative burdens significantly, but may also reduce the level of protection of human and animal health (e.g. Option 5.1 – reducing data requirements). Similarly, a policy option intended to increase the protection of human health may lead to a decrease in the availability of medicines (e.g. the options concerning potential antimicrobial resistance).

To illustrate how the emphasis given to different policy objectives might influence the selection of policy options, we have assembled three policy option packages, each
prioritising a different general objective (the objective to protect human and animal health has not been considered separately since this is assumed to underpin all policy options):

- **Option package 1**: Prioritising a reduction in administrative burdens for industry;
- **Option package 2**: Prioritising an increase in the availability of medicines; and,
- **Option package 3**: Prioritising measures to improve the free movement of goods.

Points for consideration in relation to the assembly of policy option packages include the following:

- **Amending MA procedures**: Policy options 1, 2, and 3 concern revisions to the system through which products are authorised and are, of course, mutually exclusive, since only one model can be implemented. For this analysis we have, therefore, selected the policy option that maximises the respective policy objective (free movement of goods etc). Option 4.2 concerns the introduction of a registration scheme for low-risk and generic products and could be implemented in addition to a revision to the overall MA model;

- **Addressing potential antimicrobial resistance**: The purpose of the policy options concerning antimicrobial resistance is to enhance the protection of human (and animal) health. Unlike any of the other policy options considered in this impact assessment, there is reason to believe that these measures would, in all probability, have a negative impact on the availability of medicines and increase the administrative burden imposed on businesses and other stakeholders. They are thus not included in the following analysis, though they are considered in the review of the synthesis package in Section 5.2;

- **Exclusion of unrealistic policy options**: The impact assessment exercise identified a number of policy options for which there is little or no support amongst key stakeholders, mainly because they were seen to present an unacceptable risk to the protection of human and animal health. In light of these concerns we have not considered the following policy options any further:
  - Policy Option 8.1: Abolish pharmacovigilance requirements; and,
  - Policy Option 13.1: Abolish the cascade.

A summary of the contents of the three policy option packages is provided below. Section 5.2 contains a discussion of the synthesis package of policy options.

### 5.1.1 Option package 1: Prioritising a reduction in administrative burdens for industry

This package of policy options illustrates how the reform package might be configured if the primary goal was to maximise the reduction in the administrative burden imposed on industry. A list of the policy options that have been included is shown in Table 5.24.

It is estimated that this package would reduce the administrative burden imposed on businesses by a minimum of EUR 210 million per year (i.e. from the current estimated total of EUR 538 million per year to a new figure of EUR 328 million per year – a cut of almost 40 per cent). This figure does not include the impact of a number of policy options for which it has not been possible to quantify the effect on administrative burdens.
Table 5.24  The selection of policy options that prioritise a reduction in administrative burdens imposed on industry results in a minimum estimated saving of EUR 209.7 million per year in administrative burdens (note that various savings cannot be measured)

<table>
<thead>
<tr>
<th>Policy area</th>
<th>Ref.</th>
<th>Policy sub-option(s)</th>
<th>Estimated impact on admin burdens (€m p.a.)</th>
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<tr>
<td>Authorisation procedure for new products</td>
<td>2</td>
<td>A single national Marketing Authorisation is valid throughout the EU</td>
<td>-67.9</td>
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<tr>
<td>Data requirements for authorisation</td>
<td>5.1</td>
<td>Data requirements for product authorisations are reduced</td>
<td>Decrease</td>
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<tr>
<td>Homeopathic products</td>
<td>6.1</td>
<td>Homeopathic products are excluded from the scope of the legislation</td>
<td>Decrease</td>
</tr>
<tr>
<td>Existing authorisations</td>
<td>7.1</td>
<td>Authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment</td>
<td>-14.2</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td>8.2</td>
<td>Simplify pharmacovigilance requirements</td>
<td>-47.2</td>
</tr>
<tr>
<td>MA renewals</td>
<td>9.1</td>
<td>Abolish the requirement to renew a MA</td>
<td>-69.5</td>
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<tr>
<td>Data recording and reporting</td>
<td>10.1</td>
<td>The amount of data that must be recorded and reported is reduced</td>
<td>Decrease</td>
</tr>
<tr>
<td>Packaging and labelling</td>
<td>11.1</td>
<td>Prior approval of packaging and labelling by the authorities is abolished</td>
<td>Decrease</td>
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<td></td>
<td>11.2</td>
<td>The amount of text required on packaging and labelling is reduced</td>
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<td>11.3</td>
<td>The authorities may authorise the use of non-official languages</td>
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<td>Simplifying variations requirements</td>
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<td>GRAND TOTAL</td>
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</tbody>
</table>

5.1.2  Option package 2: Prioritising an increase in the availability of medicines

This second package illustrates how the reforms might be configured if the over-riding goal was to maximise the availability of medicines. A list of the policy options that have been included is shown in Table 5.25.

The policy options shown in Table 5.25 have been selected on the basis of their direct impact on the availability of medicines. Industry has argued that any measure that decreases the administrative burden on businesses will result in resources being freed-up for re-investment in new product development, thus eventually increasing the availability of medicines. Thus, for instance, a simplification in pharmacovigilance requirements will ultimately mean that a company is able to re-invest the resources saved into research and development activity. Whilst there may be some truth in this, we have omitted these policy options that will have an indirect impact on the availability of medicines from Table 5.25, in order to focus on the proposals of direct relevance to medicine availability.

On the assumptions used in this report annual administrative burdens on the sector would fall by something in excess of EUR 80 million under this package (not all savings can be measured) – a cut of around 15 per cent on present levels.
Table 5.25  The selection of policy options that prioritise an increase in the availability of medicines results in a minimum estimated saving of EUR 82.1 million per year in administrative burdens (note that various savings cannot be measured)

<table>
<thead>
<tr>
<th>Policy area</th>
<th>Ref.</th>
<th>Policy sub-option(s)</th>
<th>Impact on medicine availability</th>
<th>Estimated impact on admin burdens (Cm p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorisation procedure for new products</td>
<td>2</td>
<td>A single national Marketing Authorisation is valid throughout the EU</td>
<td>+ +</td>
<td>-67.9</td>
</tr>
<tr>
<td>Data requirements for authorisation</td>
<td>5.1</td>
<td>Data requirements for product authorisations are reduced</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td></td>
<td>5.2</td>
<td>Under certain circumstances products are granted authorisations without the submission of full dossiers</td>
<td>+ +</td>
<td>Decrease</td>
</tr>
<tr>
<td>Homeopathic products</td>
<td>6.1</td>
<td>Homeopathic products are excluded from the scope of the legislation</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td>Existing authorisations</td>
<td>7.1</td>
<td>Authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment</td>
<td>+ +</td>
<td>-14.2</td>
</tr>
<tr>
<td></td>
<td>7.2</td>
<td>Systematically harmonise Summaries of Product Characteristics (SPCs) for authorised products</td>
<td>+</td>
<td>Short-term increase but long-term decrease for companies Increase for authorities</td>
</tr>
<tr>
<td>Packaging and labelling</td>
<td>11.1</td>
<td>Prior approval of packaging and labelling by the authorities is abolished</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td></td>
<td>11.2</td>
<td>The amount of text required on packaging and labelling is reduced</td>
<td>+ +</td>
<td>Decrease</td>
</tr>
<tr>
<td></td>
<td>11.3</td>
<td>The authorities may authorise the use of non-official languages</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td>Cascade</td>
<td>13.3</td>
<td>Increase the scope of the cascade</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Data protection</td>
<td>14.3</td>
<td>An extra 3 years of protection is added for each extension to a MA, up to a maximum of 20 years</td>
<td>+ +</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>14.5</td>
<td>Rewards for new product developments are decoupled from the initial authorisation</td>
<td>+ +</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>14.6</td>
<td>The data protection period for environmental risks is changed to match that for safety and efficacy data</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>14.8</td>
<td>The period of data protection for fish, bees and other specific species/indications is extended to 20 years</td>
<td>+ +</td>
<td>0</td>
</tr>
<tr>
<td>New treatments</td>
<td>16.1</td>
<td>Clarifying the scope of the legislation</td>
<td>+</td>
<td>0</td>
</tr>
</tbody>
</table>
5.1.3 Option package 3: Prioritising measures to improve the free movement of goods

This third package of policy options has been assembled with the aim of illustrating how reforms might be configured if the main goal was to maximise the free movement of goods. The policy options included are listed in Table 5.26. The extent to which aggregate administrative burdens rise or fall under this package is determined by the authorisation procedure adopted for new products – their expected admin burden differs significantly.

Table 5.26 The policy options that prioritise improvements to the free movement of goods result in either an increase in estimated administrative burdens of EUR 88.7 million per year, or a fall of EUR 82.1 million per year (various savings cannot be measured), depending on the combination of options selected...

<table>
<thead>
<tr>
<th>Policy area</th>
<th>Ref.</th>
<th>Policy sub-option(s)</th>
<th>Impact on free movement of goods</th>
<th>Estimated impact on admin burdens (€m p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorisation procedure for new products</td>
<td>1.1</td>
<td>The CP becomes mandatory for all products</td>
<td>+ +</td>
<td>+170.8</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>A single national Marketing Authorisation is valid throughout the EU</td>
<td>+ +</td>
<td>-67.9</td>
</tr>
<tr>
<td>Homeopathic products</td>
<td>6.1</td>
<td>Homeopathic products are excluded from the scope of the legislation</td>
<td>+ +</td>
<td>Decrease</td>
</tr>
<tr>
<td>Existing authorisations</td>
<td>7.1</td>
<td>Authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment</td>
<td>+ +</td>
<td>-14.2</td>
</tr>
<tr>
<td></td>
<td>7.2</td>
<td>Systematically harmonise Summaries of Product Characteristics (SPCs) for authorised products</td>
<td>+ +</td>
<td>Short-term increase but long-term decrease for companies Increase for authorities</td>
</tr>
<tr>
<td>Data recording and reporting</td>
<td>10.1</td>
<td>The amount of data that must be recorded and reported is reduced</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td>Packaging and labelling</td>
<td>11.1</td>
<td>Prior approval of packaging and labelling by the authorities is abolished</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td></td>
<td>11.2</td>
<td>The amount of text required on packaging and labelling is reduced</td>
<td>+ +</td>
<td>Decrease</td>
</tr>
<tr>
<td></td>
<td>11.3</td>
<td>The authorities may authorise the use of non-official languages</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td>New treatments</td>
<td>16.1</td>
<td>Clarifying the scope of the legislation with</td>
<td>+ +</td>
<td>Decrease</td>
</tr>
</tbody>
</table>
### 5.2 A synthesis package of policy options

5.2.1 Estimates suggest a synthesis package of options could cut administrative burdens on the sector by more than a third whilst also contributing to the availability of medicines and the integrity of the single market.

The three packages of policy options shown in Section 5.1 illustrate how prioritisation of policy objectives might influence the selection of options. In practice, a package of policy options that prioritises one policy objective over all others is likely to be neither desirable nor achievable, and instead a balance should be sought between each of the policy objectives for the legislative revision.

A synthesis package of policy options which meets that challenge has been identified and is shown in Table 5.27. These options collectively result in a decrease in the estimated administrative burdens imposed on industry in excess of EUR 193.5 million per year (i.e. from the current total of EUR 537.9 million per year to a new figure of EUR 344.4 million per year – a cut of 36 per cent). This figure understates the expected value of the change as there are policy options which are expected to reduce burdens but the scale of the impact cannot be quantified.

The majority of the policy options included in this impact assessment address particular aspects of the problem, and thus can be considered to be relatively ‘free-standing’. Removing or replacing options included within the synthesis package thus would not affect the effectiveness of other options, though there would be an impact on the aggregate benefits achieved.

There are some instances where there would be links between options. For example, pharmacovigilance and MA renewals are used to collect data on the performance of products once they have been placed on the market. Abolishing one or both would thus reduce the amount of safety information received by regulators once they have authorised a product, making them less likely to accept policy options that simplify requirements for the initial MA (e.g. through reduced data submissions). However, since the abolition of pharmacovigilance and MA renewals have not been included within the synthesis package, this issue does not warrant further consideration.

5.2.2 Clearer specification of some of the options in the synthesis package would be needed to engender support for them in negotiation and facilitate their subsequent implementation.

The analysis presented in Section 4 and Annex 12 identified a number of issues with the design of many of the policy options included in this impact assessment. In many cases...
there was broad agreement amongst stakeholders on the need for certain policy options, but
a lack of a consensus as to how they should be implemented.

Table 5.27 identifies a number of conditions needed for those policy options to be viable
and/or successfully implemented. It draws on the evidence collected during the consultation
exercise and the judgement of the study team. A more detailed discussion of the issues is
provided below.

5.2.2.50 A new MA procedure for new products

There is a strong case for making the a single MA valid for the entire EU/EEA, but it is
recognised that this change could usefully be accompanied by confidence-building measures
that help to address the concerns of authorities about decisions taken in other Member
States. This lack of trust can be addressed in two separate ways:

- Policy option 2.1 proposes the creation of an accreditation system which would ensure
  that the assessment systems of national competent authorities are of an appropriate
  standard. Accreditation could be based on international standard systems (e.g. the ISO
  standard system). Further work will be needed in order to develop this accreditation
  system, but there is a strong argument that the work should be carried out by a pan-EU
  body rather than by individual Member States. The accreditation body would need to be
  able to withdraw the power to award MAs from competent authorities that did not meet
  the required standards, and it is difficult to see how this would operate if managed by
  Member States. The EU accreditation system could be supported by a good practice
  sharing system managed by the Member States (based on BEMA);

- Alongside Option 2.1 there is a strong case for the introduction of a system of peer-
  review. Concerns have been expressed by stakeholders about quality control at the
  level of individual MA assessments. Further work will be needed in order to establish
  how this system would work in practice, but in principle each assessment could be
  carried out by two competent authorities, to ensure that appropriate quality
  control checks were in place.

There is also the option of – initially – restricting the new MA system to ‘lower risk’ product
categories (which industry has estimated constitute the vast majority of products), in order to
overcome concerns from Member States about a loss of national control over antimicrobials
and other products of particular concern. In that model, assessments of higher-risk product
categories would instead be carried out either by the EMA (necessitating a change in the
scope of the Centralised Procedure), or by some form of retained National Procedure/ MRP/
DCP system.

This and other policy options thus require a system through which ‘lower risk’ products can
be defined. There is at present no system in place for defining ‘lower risk’ products, and so
this would need to be created. This role could potentially be filled by a competent body at an
EU level, with the assessment criteria agreed between the various stakeholder groups.

5.2.2.51 Reduced data requirements for authorisations

Further clarification of this policy option is needed to identify exactly which data will be
omitted. Reductions in data requirements are supported, particularly in respect of
administrative data. Further reductions in safety, quality and/or efficacy data could be
introduced based on the benefit-risk balance of a product, thus reducing requirements for
lower-risk products.

Also included within this policy option is a proposal for authorisations to be granted without
the submission of full dossiers in exceptional circumstances. In order to avoid market
distortions an appropriate definition of ‘exceptional circumstances’ would be required, but
otherwise this policy option is widely supported.

5.2.2.52 Procedures for products with existing MAs

Broadening the extent and coverage of existing MAs should be a priority for the legislative
revision. Allowing authorised products to freely circulate throughout the EU/EEA would have
a significant impact. As noted above, there is a certain lack of trust amongst competent
authorities – particularly regarding historical authorisations – which would need to be addressed. Pharmacovigilance records are not regarded as an accurate measure of safe use, and in addition it may be necessary to restrict this policy option to lower-risk product categories. It is also recommended that this proposal be restricted – initially – to products authorised during the timeframe of EU veterinary pharmaceutical legislation (either 2001/2004, then at a later date extended to back to 1981).

The systematic harmonisation of SPCs is a necessary but complex task. Lessons can doubtless be drawn from the experience of the CMDv’s ‘pilot’ programme of voluntary SPC harmonisation. This activity could – initially – focus on priority product types, as defined by availability gaps or cases where there are significant divergences between countries (e.g. in respect of withdrawal periods). The resourcing of the SPC harmonisation process could potentially be based on a voluntary industry levy, based on the resources saved through reductions in the administrative burden. The criteria used to select which SPC to harmonise against must be carefully considered. Provided products were authorised during the timeframe of EU veterinary pharmaceutical legislation (see above), industry should be free to choose which SPC to select, but for historical authorisations where data may not comply with current standards a re-assessment may be required in order to satisfy the concerns of competent authorities.

5.2.2.53 Revisions to pharmacovigilance requirements

Whilst this option is popular and viable, in order to overcome the concerns of many regulators it may be necessary to restrict reduced pharmacovigilance reporting (e.g. the abolition of PSURs) to lower risk product categories. Current requirements should be retained for higher-risk product categories and products with new ingredients, though there are clearly measures that would simplify the process and reduce administrative burdens. These include common dates for PSUR submissions across all countries and increased usage of electronic submissions. It may also be possible to improve the efficiency of PSUR processing, for instance through the introduction of a coordinated system under which a single national authority (identified according to product category expertise) is responsible for assessing PSURs, rather than this being done on multiple occasions.

5.2.2.54 Revisions to MA renewal requirements

Concerns from regulators about the health protection implications of a complete abolition of renewals mean that it is recommended that renewals are retained for higher risk product categories. ‘Higher risk’ would need to be defined by a competent body at EU level.

5.2.2.55 Data recording and reporting

This policy option needs further clarification in order to identify exactly which data will be omitted, but reductions in data requirements are supported, particularly in respect of administrative data.

5.2.2.56 Simplification of packaging and labelling requirements

Regulators expressed concerns about the impacts of these proposals on health protection which would need to be addressed were these options to be implemented. It may be necessary to initially restrict these changes to products that are administered by veterinarians and/or to increase the amount of information available through alternative sources (e.g. drug compendia or product barcodes).

5.2.2.57 Revisions to MA Variations

For health protection reasons, regulators reported that they always need to be informed of any changes to MAs, and so whilst revisions should be made by MA holders, this would need to be accompanied by electronic notification.

5.2.2.58 Amendments to data protection

For the most part the implementation of these proposals should not pose a problem, though clear definitions will need to be established where certain product types (e.g. MUMS uses) are eligible for extended data protection periods.
5.2.2.59 Clarification of scope with regard to new treatments

Aside from issues around legal definitions of new treatments within what is a fast-moving and innovative field, there were no major implementation issues with this policy option.

5.2.2.60 Changes to control and monitoring measures

The only major implementation issue concerns the EU database of MAs. Whilst this was widely supported, work will need to be done in order to ensure that it is fit for purpose. This work will include the development of harmonised data definition and reporting protocols, since it is clear from the work carried out for this study that national databases are highly variable in terms of coverage (the parameters included within the databases) and definitions (how a product MA is defined).

It is also likely that some Member States will not provide data, or will not update their databases once the initial upload has been completed (e.g. due to resource or capacity problems). Once the database has been established we recommend that the Commission circulates regular updates within the veterinary pharmaceutical community highlighting coverage issues.

As an interim step it may be necessary for the Commission to request that Member States which are non-compliant provide their national databases (e.g. as Microsoft Excel files) and publish them.
Table 5.27  A synthesis package of policy options, which results in a decrease in the administrative burdens imposed on businesses worth EUR 193.5 million per year (note that various savings cannot be measured)

<table>
<thead>
<tr>
<th>Policy area</th>
<th>Ref.</th>
<th>Policy option</th>
<th>Conditions for effective implementation</th>
<th>Impact on free movement of goods</th>
<th>Impact on availability of medicines</th>
<th>Estimated impact on admin burdens (€m p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authorisation procedure for new products</td>
<td>2.1</td>
<td>Making a single marketing authorisation valid throughout the EU/EEA. The quality of the work of the competent authorities would be ensured by an independent EU body</td>
<td>Peer review by a second competent authority as part of the assessment process. Potentially restricted to lower-risk product categories, with higher-risk products either the responsibility of the EMA, or a retained MRP/DCP</td>
<td>+ +</td>
<td>+ +</td>
<td>-67.9</td>
</tr>
<tr>
<td>Data requirements for authorisation</td>
<td>5.1</td>
<td>Data requirements for product authorisations are reduced</td>
<td>Potentially restrict to lower-risk product categories</td>
<td>o</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td></td>
<td>5.2</td>
<td>Under certain circumstances products are granted authorisations without the submission of full dossiers</td>
<td>Based on an appropriate definition of ‘exceptional circumstances’, in order to avoid market distortions</td>
<td>+</td>
<td>+ +</td>
<td>Decrease</td>
</tr>
<tr>
<td>Existing authorisations</td>
<td>7.1</td>
<td>Authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment</td>
<td>Potentially restrict to lower-risk product categories Restrict to products authorised since 2001 or 2004, then perhaps since 1981</td>
<td>+ +</td>
<td>+ +</td>
<td>Decrease</td>
</tr>
<tr>
<td></td>
<td>7.2</td>
<td>Systematically harmonise Summaries of Product Characteristics (SPCs) for authorised products</td>
<td>Funded through voluntary industry levy? For products authorised since 2001 or 2004, then perhaps since 1981, industry could choose which SPC to harmonise against, but in other cases re-assessment may be needed</td>
<td>+ +</td>
<td>+ +</td>
<td>Short-term increase but long-term decrease for firms Increase for authorities</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td>8.2</td>
<td>Simplify pharmacovigilance requirements</td>
<td>Potentially restrict to lower-risk product categories</td>
<td>o</td>
<td>o</td>
<td>-47.2</td>
</tr>
</tbody>
</table>
### Table: Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

<table>
<thead>
<tr>
<th>Policy area</th>
<th>Ref.</th>
<th>Policy option</th>
<th>Conditions for effective implementation</th>
<th>Impact on free movement of goods</th>
<th>Impact on availability of medicines</th>
<th>Estimated impact on admin burdens (€m p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MA renewals</td>
<td>9.2</td>
<td>Restrict the requirement to renew a MA to specific cases based on the risk profile of the product</td>
<td>Renewals retained for higher-risk product categories</td>
<td>o</td>
<td>o</td>
<td>-67.5</td>
</tr>
<tr>
<td>Data recording and reporting</td>
<td>10.1</td>
<td>The amount of data that must be recorded and reported is reduced</td>
<td>To be determined which data will be affected</td>
<td>+</td>
<td>o</td>
<td>Decrease</td>
</tr>
<tr>
<td>Packaging and labelling</td>
<td>11.1</td>
<td>Prior approval of packaging and labelling by the authorities is abolished</td>
<td>Consider restricting to products administered by veterinarians as a first step.</td>
<td>+</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The amount of text required on packaging and labelling is reduced</td>
<td>Consider restricting to products administered by veterinarians as a first step.</td>
<td>+</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>A harmonised ‘library’ of pictograms will need to be developed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Investigate other sources of information (e.g. drug compendia or product barcodes)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>11.3</td>
<td>The authorities may authorise the use of non-official languages</td>
<td>Consider restricting to products administered by veterinarians as a first step.</td>
<td>+</td>
<td>+</td>
<td>Decrease</td>
</tr>
<tr>
<td>MA Variations</td>
<td>12.1</td>
<td>Simplifying variations requirements</td>
<td>A system whereby competent authorities are notified electronically of any changes to the MA would be needed</td>
<td>o</td>
<td>o</td>
<td>-10.9</td>
</tr>
<tr>
<td>Data protection</td>
<td>14.5</td>
<td>Rewards for new product developments are decoupled from the initial authorisation</td>
<td>None</td>
<td>o</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The data protection period for environmental risks is changed to</td>
<td>None</td>
<td>o</td>
<td>+</td>
<td>Decrease for generics developers</td>
</tr>
<tr>
<td>Policy area</td>
<td>Ref.</td>
<td>Policy option</td>
<td>Conditions for effective implementation</td>
<td>Impact on free movement of goods</td>
<td>Impact on availability of medicines</td>
<td>Estimated impact on admin burdens (€m p.a.)</td>
</tr>
<tr>
<td>--------------------------</td>
<td>------</td>
<td>-------------------------------------------------------------------------------</td>
<td>------------------------------------------</td>
<td>----------------------------------</td>
<td>-------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td></td>
<td></td>
<td>match that for safety and efficacy data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>14.8</td>
<td>The period of data protection for fish, bees and other specific species/indications is extended to 20 years</td>
<td>Should apply to all MUMS, which would require a harmonised definition of MUMS to be developed</td>
<td>0</td>
<td>+ +</td>
<td>0</td>
</tr>
<tr>
<td>New treatments</td>
<td>16.1</td>
<td>Clarifying the scope of the legislation with regard to new types of treatment</td>
<td>None</td>
<td>+ +</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Control and monitoring</td>
<td>18.1</td>
<td>National control systems are required to meet agreed European standards, and the Commission has the powers to check such systems</td>
<td>None</td>
<td>+</td>
<td>0</td>
<td>Increase for authorities</td>
</tr>
<tr>
<td></td>
<td>18.2</td>
<td>Harmonised EU sanctions are introduced for non-compliance</td>
<td>None</td>
<td>+</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>19.1</td>
<td>Enforcing a European database of authorised products</td>
<td>Harmonised data definition and reporting protocols are needed</td>
<td>0</td>
<td>0</td>
<td>Increase for authorities</td>
</tr>
<tr>
<td></td>
<td></td>
<td>The Commission should circulate summaries of national database coverage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**GRAND TOTAL**  
-193.5
5.3 Other options not in the synthesis package have some potential to deliver positive change but would need further development to be viable

The synthesis package of policy options shown in Table 5.27 provisionally omits a number of proposals that require further consideration and development before they can either be included or excluded from the legislative reform package. These options are reviewed in Table 5.28.

Table 5.28 A number of the policy options included in this impact assessment require further development before they can be included or excluded from the legislative reform package

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Policy option</th>
<th>Development issues and requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2</td>
<td>A system of registration replaces authorisations for low-risk/ generic products</td>
<td>This policy option would, in effect, replace the current authorisation system with a light-touch registration scheme, without any scientific assessment of products. Most of the stakeholders consulted for this study expressed concerns about the impact that this move would have on health protection, even were this option restricted to low risk products (generics were not considered to be automatically low risk). Further development work around the nature of the registration scheme would be needed before this option could be implemented. This policy option would have a significant positive impact on the free movement of goods, the availability of medicines and the administrative burden imposed on companies. The magnitude of the likely impacts mean that this option should at least be subject to further consideration.</td>
</tr>
<tr>
<td>6</td>
<td>Simplifying requirements for homeopathic products</td>
<td>The level of risk associated with homeopathic products requires further consideration before policy options that simplify requirements for the authorisation of homeopathic products can properly be considered. For the most part the stakeholders consulted for this study did not wish to see any further reduction in requirements, but this was not a representative cross-section of stakeholders from the homeopathic sector.</td>
</tr>
<tr>
<td>13</td>
<td>Amending the scope of the cascade</td>
<td>Three policy options relating to the cascade were considered in this impact assessment. Abolition of the cascade was rejected by all consultees, whilst an extension of the scope of the cascade was seen by many stakeholders to be potentially risky for the protection of health. If there is a problem with the cascade – and the lack of data means that this has been impossible to determine – it is likely to be with the way in which the law is enforced in Member States, rather than the law itself (which already places restrictions on the usage of medicines off-label). Anecdotally there are differences in the thoroughness with which countries enforce the cascade, and harmonised/ stronger guidelines in this area would have more of an impact than further restrictions on the scope of the cascade.</td>
</tr>
<tr>
<td>17</td>
<td>Addressing the potential problem of antimicrobial resistance</td>
<td>Five policy options concerning antimicrobial resistance were included within this impact assessment. There was broad support for two options – Option 17.2 (consideration of antimicrobial resistance as part of the authorisation process) and Option 17.3 (the collection of data on antimicrobial usage). Policy option 17.1 (the prohibition of the use of critical human antimicrobials in animals) was rejected by most stakeholders, primarily on animal welfare grounds, but also due to a widespread perception that there was insufficient...</td>
</tr>
</tbody>
</table>
Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

Ref. Policy option Development issues and requirements

scientific evidence as regards the link between antimicrobial usage in animals and the development of resistance. A case has been made that banning veterinarians from selling antimicrobials (Option 17.4) would have a detrimental impact on the viability of rural veterinary practices. It seems unlikely that an outright ban on the advertising of antimicrobials to veterinarians (Option 17.5) would have a major impact on the usage of such medicines.

Whilst there is merit to some of these proposals, the causes of antimicrobial resistance and the contribution of animal pharmaceuticals to this resistance need to be researched in more detail before recommendations can be made as to how to legislate to address the problem.

5.4 Indicators for future monitoring and evaluation

Monitoring indicators enable policy makers to assess whether an intervention is proceeding as intended, and whether there are any unintended impacts. In this case, indicators can be used to monitor whether the legislative revision, once implemented, addresses the problems that were reviewed in Section 2. Evaluation is an in-depth analytical exercise that will be carried out once sufficient time has elapsed in order to thoroughly review the performance of the new legislative framework for veterinary medicinal products.

Table 5.29 provides details of a set of indicators that could be collected and used to monitor the impacts of the legislative revision. These indicators have been presented according to the general objective (see Section 3.1) that they are intended to address. In each case we provide detail on the source of data, the purpose of collection/analysis, and the likely difficulty that will be experienced in obtaining the information required.

All indicators would need to be collated and analysed centrally by the European Commission, and could be published in the form of a regular report. In most cases the information required is held by national competent authorities, and so reporting protocols would need to be established. As discussed in Annex 1, the quality and comprehensiveness of national MA databases is currently highly variable, and considerable work would need to be undertaken if data reporting standards were to meet the standards required (improvements that form part of Policy Option 19 – see Section 4.2.19). The completion of a single EU database would simplify the monitoring process.

Table 5.29 Proposed indicators for monitoring the impacts of the legislative revision

<table>
<thead>
<tr>
<th>General policy objective</th>
<th>Proposed monitoring indicator</th>
<th>Method of data collection</th>
<th>Purpose of data collection/analysis</th>
<th>Difficulty of data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>To improve the functioning of the single market in veterinary medicinal products</td>
<td>Proportion of MA holders who hold MAs on more than one national market</td>
<td>Analysis of national MA databases (eventually the EU-wide MA database)</td>
<td>Analysis of the extent to which companies operate in multiple EU countries, and comparison with the baseline in this report</td>
<td>Low, provided EU database exists</td>
</tr>
<tr>
<td>To enhance the level of protection for humans, animals and the environment</td>
<td>Total number of MAs, disaggregated by country, species etc.</td>
<td>Analysis of national MA databases (eventually the EU-wide MA database)</td>
<td>Analysis of whether the total number of MAs changes over time, and comparison with the baseline in this report</td>
<td>Low, provided EU database exists</td>
</tr>
<tr>
<td></td>
<td>Number of MAs in a sample of small countries (e.g. MT, CY, IS, EE)</td>
<td>Analysis of national MA databases (eventually the EU-wide MA database)</td>
<td>Analysis of the number of MAs within small markets changes over time, and comparison with the baseline in this report</td>
<td>Low, provided EU database exists</td>
</tr>
<tr>
<td>General policy objective</td>
<td>Proposed monitoring indicator</td>
<td>Method of data collection</td>
<td>Purpose of data collection/ analysis</td>
<td>Difficulty of data collection</td>
</tr>
<tr>
<td>--------------------------</td>
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</tr>
<tr>
<td></td>
<td>Number of MAs for MUMS uses</td>
<td>Analysis of national MA databases, using a standard MUMS definition</td>
<td>Analysis of the number of MAs for MUMS changes over time, and comparison with the baseline in this report</td>
<td>Low, provided EU database exists</td>
</tr>
<tr>
<td></td>
<td>Analysis of extent to which products are marketed</td>
<td>Competent authorities would need to record data on product 'presence' on market, and include in national MA databases</td>
<td>Analysis of whether authorised products are actually available (e.g. on small markets)</td>
<td>High, requires Member States to start collecting data</td>
</tr>
<tr>
<td></td>
<td>Applications for new MAs, disaggregated by country, species, outcome etc.</td>
<td>Competent authority (EMA/ CMDv) databases on applications received National databases would need to be created</td>
<td>Analysis of 'innovation' – as measured by new applications</td>
<td>High, requires creation of national databases for applications</td>
</tr>
<tr>
<td>To reduce the administrative burden imposed on businesses</td>
<td>Total administrative burden (EUR p.a.) imposed on industry</td>
<td>Periodic electronic survey of businesses</td>
<td>Periodic development of a SCM and comparison with the baseline in this report to assess whether burden is decreasing</td>
<td>Medium</td>
</tr>
<tr>
<td></td>
<td>Administrative burden for businesses in obtaining a MA (i.e. new applications)</td>
<td>Periodic electronic survey of businesses</td>
<td>SCM focussing on the costs of obtaining a MA, to assess whether legislation is a barrier to new product development</td>
<td>Medium</td>
</tr>
<tr>
<td></td>
<td>Administrative burden for businesses in maintaining a MA (i.e. renewals, variations, pharmacovigilance)</td>
<td>Periodic electronic survey of businesses</td>
<td>SCM focussing on costs of maintaining a MA, to assess whether legislation is a barrier to keeping products on the market</td>
<td>Medium</td>
</tr>
</tbody>
</table>
6 Concluding remarks

This report summarises the content and results of an impact assessment into proposed revisions to the legislative framework for veterinary medicinal products.

The analysis supports the case for legislative reform. The evidence presented shows that the animal pharmaceutical sector faces a number of problems. Much of that evidence is either completely new (such as the magnitude of the administrative burdens facing businesses) or has not been collected and analysed in this way before (such as the total number of authorised products in the EU).

The European Commission has developed a schedule of potential policy options that could be adopted to reform the legislation. This study has demonstrated how, and where, packages built from these options could address the problems faced in this market. It has shown that such packages could make a significant difference – addressing the major problems in terms of the availability of medicines, the operation of the single market, and the administrative burdens imposed on businesses.

Consultation with a wide range of stakeholders suggests that there is considerable support for the measures proposed, though there are also issues regarding the details of implementation that will need to be addressed before a consensus as to the way forward can be reached.
ANNEXES
Annex 1  Method of approach to the study

The method of approach to the study was summarised in Section 1.1. The purpose of this Annex is to provide additional commentary on the methodology employed, including identification of any problems identified.

The Terms of Reference for this assignment required two key methodological stages:

- The collection of data to substantiate the current ‘problem’ facing the legislation. As noted in the Terms of Reference, ‘it is of paramount importance that the proposed methodological approach is focussed on gathering quantitative data’; and,

- The collection and presentation of data analysing the impact of the proposed policy options for the legislative revision.

Annex 3 to the Terms of Reference included a table showing databases that the study was required to populate, in order to measure the ‘problem’. Table A1.1 summarises the method of approach employed in order to collect each of the datasets outlined in Annex 3 to the Terms of Reference. The table also identifies the corresponding section(s) of this report where data can be found. Where there are gaps in the collection of data caused by a lack of availability, we also suggest possible ways in which these gaps might be filled in the future (which links with the proposals in terms of the collection of monitoring and evaluation data – see Section 5.4).
Table A1.1  Summary of the method of approach employed in order to meet the data collection requirements set out in Annex 3 of the Terms of Reference, the corresponding section of this report where data can be found, and suggested approaches for the future collection of missing data

<table>
<thead>
<tr>
<th>Database</th>
<th>Details of data requirements</th>
<th>Method of approach employed by this study</th>
<th>Corresponding section(s) of the report</th>
<th>Potential future data collection measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of new pharmaceutical products</td>
<td>Number of authorisations in the EU broken down by authorisation procedure, active ingredients, new species, vaccines, and the role of SMEs</td>
<td>There is no centralised EU-wide source of data on product authorisations. Instead, all 30 EU/EEA national competent authorities were asked to submit electronic databases of product authorisations. A total of 19 countries provided databases, and a further 5 countries sent data in a format that could not readily be analysed (e.g. data were provided in PDF format). The coverage of databases varied (see Annex 2 for an overview). None of the databases contained information on active ingredients. It was also impossible to ascertain which of the MA holders were SMEs.</td>
<td>Section 2.1 and Annex 5</td>
<td>Centralised EU-wide database of product authorisations</td>
</tr>
<tr>
<td>Geographic coverage of pharmaceutical products</td>
<td>Data on the number of authorised medicines in each Member State, disaggregated by active ingredients, extensions, new species and vaccines</td>
<td>Data on product authorisations and new applications included information on the country within which the authorisation was granted.</td>
<td>Section 2.1.1 and Annex 5</td>
<td>Centralised EU-wide database of product authorisations</td>
</tr>
<tr>
<td>Product range in relation to animal species and diseases</td>
<td>Data on the availability of medicines for the treatment of diseases affecting a sample of animals (at least 10 species)</td>
<td>Data on product authorisations and new applications included analysis of the number of products targeted at 12 species categories (the categories were chosen to ensure that the major livestock species were included, together with the major companion animal species and a selection of exemplar minor species): dogs; cats; cattle; pigs; sheep; horses; goats; chickens; turkeys; bees; salmon, trout and other fish species; and all other species. Authorisation databases did not include any data on diseases (only therapeutic categories as classified through the ATCvet system).</td>
<td>Section 2.1.2 and Annex 5</td>
<td>Centralised EU-wide database of product authorisations</td>
</tr>
<tr>
<td>Database</td>
<td>Details of data requirements</td>
<td>Method of approach employed by this study</td>
<td>Corresponding section(s) of the report</td>
<td>Potential future data collection measures</td>
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<td>------------------------------------------</td>
</tr>
<tr>
<td>Risks for animal health</td>
<td>The relationship between animal health and the availability of veterinary medicinal products</td>
<td>It was agreed following the submission of the First Activity Report that a case study would be undertaken of the risks to animal health posed by bluetongue. The case study was based on a review of literature and discussions with experts from industry and regulatory bodies.</td>
<td>Section 2.1 and Annex 9</td>
<td>Qualitative issue – no data collection possible</td>
</tr>
<tr>
<td>Risks for public health</td>
<td>The relationship between public health and the availability of veterinary medicinal products</td>
<td>It was agreed following the submission of the First Activity Report that a case study would be undertaken of the risks to human health posed by avian influenza. The case study was based on a review of literature and discussions with experts from industry and regulatory bodies.</td>
<td>Section 2.1 and Annex 9</td>
<td>Qualitative issue – no data collection possible</td>
</tr>
<tr>
<td>Data protection</td>
<td>The impacts on the availability of medicines of extending the period of data protection</td>
<td>The set of policy options for consideration in the impact assessment included proposals for extending the period of data collection. The impacts of these proposals on the availability of medicines were thus considered as part of the stakeholder consultation exercise, and the views of representatives from industry, regulatory bodies, and end user organisations were sought. It was not possible to quantify this impact.</td>
<td>Section 4.2.14</td>
<td>The effect of this policy option could be monitored through data on the number of products authorised for use with MUMS</td>
</tr>
<tr>
<td>Levels of investment by the animal pharmaceutical industry</td>
<td>Investment patterns by animal pharmaceutical companies within the EU</td>
<td>A desk review was undertaken of publicly available data on the structure of the animal pharmaceutical industry, including material published by a trade association for the sector – IFAH-Europe. Unfortunately there was no information available on investment levels, only employment and sales. It was not possible to use Eurostat data since the animal pharmaceutical industry was not separated from the human pharmaceutical industry.</td>
<td>Annex 8</td>
<td>Investigate with IFAH-Europe whether investment could be included within sector data collection activity</td>
</tr>
<tr>
<td>Time to approval</td>
<td>The time taken to obtain an authorisation, from the time that applications were submitted</td>
<td>Data on the number of days elapsed between the receipt of an application by the authorities and the decision were only available for the Centralised Procedure (from the EMA) and the National Procedure in the UK. Time to approval data were thus not available in respect of the MRP and DCP, and for the remaining 26 EU Member States.</td>
<td>Annex 6</td>
<td>Systematic collection of data on duration of procedure for all applications</td>
</tr>
<tr>
<td>Time, costs and risks to develop veterinary medicinal products</td>
<td>Regulation-driven time, costs and risks to develop veterinary medicinal products, and to</td>
<td>The regulation-driven time and costs of obtaining a new authorisation and extending the scope of existing authorisations was measured through the development of a SCM for the sector</td>
<td>Section 2.3 and Annex 7</td>
<td>Periodic update of SCM developed for this study,</td>
</tr>
<tr>
<td>Database</td>
<td>Details of data requirements</td>
<td>Method of approach employed by this study</td>
<td>Corresponding section(s) of the report</td>
<td>Potential future data collection measures</td>
</tr>
<tr>
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</tr>
<tr>
<td>products</td>
<td>broaden the scope of existing product authorisations</td>
<td>(see below). The risks generated by the legislation can partially be measured according to the probability of an application being successful. This information was available for applications submitted through the MRP, DCP and in the UK through the National Procedure.</td>
<td>Annex 6</td>
<td>based on primary research with businesses</td>
</tr>
<tr>
<td>Costs for maintaining existing products on the market</td>
<td>The number of dossiers submitted for renewal, compared to the potential number of renewals</td>
<td>Data on the number of applications for MA renewal were collected for the Centralised Procedure, the MRP and the DCP, and for the UK in respect of the National Procedure</td>
<td>Annex 6</td>
<td>Competent authorities to periodically submit data on applications received</td>
</tr>
<tr>
<td>Costs for maintaining existing products on the market</td>
<td>Regulation-driven costs of maintaining products on the market</td>
<td>Data on the costs incurred by industry as part of the renewal of an existing MA were included within the SCM, based on a survey of companies (see below)</td>
<td>Section 2.3 and Annex 7</td>
<td></td>
</tr>
<tr>
<td>Description of the authorisation system in the Member States</td>
<td>Data on the resourcing of authorisation systems, levels of scientific expertise, confidence in the activities of other Member States, coordination with other competent authorities, and fee systems applied</td>
<td>There is no centralised EU-wide source of data on the resources and capacity within national authorisation systems. This data, together with information on scientific capacity, coordination and fees could only be collected directly from national competent authorities, and in practice much of this information would consist of qualitative descriptions, rather than data. Competent authorities often have difficulty in quantifying relevant resource commitments (e.g. where staff also have other regulatory responsibilities)</td>
<td>Not available</td>
<td>Competent authorities could submit reports to EU detailing resourcing and capacity of systems</td>
</tr>
<tr>
<td>Diverging approaches towards the harmonisation of authorisation systems</td>
<td>Examples of variations in SPCs between countries due to divergences in national approaches</td>
<td>Lack of electronic versions of SPCs meant that it was not possible to systematically investigate variations between countries. The impacts of variations in SPCs between countries was considered with stakeholders as part of the consultation exercise. For instance, one of the policy options considered included a proposal to harmonise all SPCs, and stakeholders were asked to assess the effect that this would have.</td>
<td>Section 4.2.7.17</td>
<td>EU database of product authorisations to include SPCs</td>
</tr>
<tr>
<td>Off-label usage of medicines</td>
<td>Data on the frequency with which veterinarians make use of the cascade, disaggregated between Member States</td>
<td>There is no centralised EU-wide source of data the usage of the cascade. Veterinarians are required to keep records of cascade usage for at least 5 years, but there are no requirements in the legislation for the centralised collation of this data. GHK contacted all national veterinary associations to confirm that there is no obligation for veterinarians to report cascade usage to the</td>
<td>Not available</td>
<td>Systematic collection and reporting of data on the cascade by veterinarians, potentially focusing</td>
</tr>
</tbody>
</table>
### Database Details of data requirements Method of approach employed by this study Corresponding section(s) of the report Potential future data collection measures

<table>
<thead>
<tr>
<th>Diverging approaches towards pharmacovigilance, packaging and labelling, and the distribution chain</th>
<th>Examples on the extent to which there is variation between countries in respect of their approaches towards pharmacovigilance, packaging and labelling, and the distribution chain</th>
<th>It was not possible to quantify divergent approaches between Member States towards pharmacovigilance, packaging and labelling and the pharmaceutical distribution chain. These issues were discussed as part of the stakeholder consultation exercise, since the policy options include proposals to harmonise national approaches, particularly within the areas of packaging and labelling. Whilst there were no policy options to harmonise the legislative approach towards the distribution chain, this issue was considered within a number of policy options, for instance in relation to whether it would be possible to prevent veterinarians from selling antimicrobials (in some countries this would currently not be possible since pharmacists are prevented from selling veterinary products).</th>
<th>Section 4.2.8, Section 4.2.11 and Section 4.2.17</th>
<th>Qualitative issue – no data collection possible</th>
</tr>
</thead>
<tbody>
<tr>
<td>The administrative burden imposed by the legislation</td>
<td>The application of the SCM in order to measure the administrative burden imposed on businesses and competent authorities</td>
<td>The administrative burdens generated through complying with the legislation were measured for businesses through a survey of companies. An electronic survey was designed for circulation amongst businesses. IFAH-Europe distributed the survey to their corporate members, and to national industry associations, who in turn distributed it to their members. A total of 17 companies responded to the survey. Using this data, a SCM was developed</td>
<td>Section 2.3, Section 2.3 and Annex 7</td>
<td>Periodic update of SCM developed for this study, based on primary research with businesses</td>
</tr>
</tbody>
</table>

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The European Commission has undertaken a parallel exercise with national competent authorities. No countries have been identified where veterinarians must report cascade usage. The only way to collect this information would thus be direct from veterinarians. This exercise would have required a statistically representative EU-wide survey of veterinarians, and it was agreed following the submission of the Second Activity Report that this would have been prohibitively expensive.

A case study was undertaken of the use of antibiotic footbath through the cascade in the United Kingdom. The case study was based on a review of literature. Qualitative evidence on the usage of the cascade was collected as part of the stakeholder consultation exercise, including through discussions held with veterinarian organisations.

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Diverging approaches towards pharmacovigilance, packaging and labelling, and the distribution chain

Examples on the extent to which there is variation between countries in respect of their approaches towards pharmacovigilance, packaging and labelling, and the distribution chain.

It was not possible to quantify divergent approaches between Member States towards pharmacovigilance, packaging and labelling and the pharmaceutical distribution chain. These issues were discussed as part of the stakeholder consultation exercise, since the policy options include proposals to harmonise national approaches, particularly within the areas of packaging and labelling. Whilst there were no policy options to harmonise the legislative approach towards the distribution chain, this issue was considered within a number of policy options, for instance in relation to whether it would be possible to prevent veterinarians from selling antimicrobials (in some countries this would currently not be possible since pharmacists are prevented from selling veterinary products).

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**Database**

**Details of data requirements**

**Method of approach employed by this study**

**Corresponding section(s) of the report**

**Potential future data collection measures**
**Database** | **Details of data requirements** | **Method of approach employed by this study** | **Corresponding section(s) of the report** | **Potential future data collection measures**
---|---|---|---|---
SMEs | Data on the number of SMEs in the animal pharmaceutical industry, the proportion of total employment within SMEs, and the role of SMEs within the supply chain | Databases of national MA holders that were provided by the Member States did not include any information on whether the businesses were SMEs or not. Similarly, the employment data collected by IFAH-Europe did not distinguish between SMEs and larger companies, and Eurostat employment data does not distinguish between the animal and human pharmaceutical industries. The EMA maintain a register of SMEs, but this is voluntary, and in practice it is likely that only those companies with an interest in participating in European procedures would participate. Consequently there is no comprehensive source of information on the number of MA holders that are SMEs. | Not available | Competent authorities to collect and record information on whether MA holders are SMEs, using EU definition.

The possibility of the legislation to respond to new needs and challenges | Analysis of whether the legislation is sufficiently designed to respond to new needs and new technologies | The impact assessment phase of the study included consideration of a policy option which sought to make the legislation more suitable for new and emerging needs and challenges. This policy option was reviewed as part of the stakeholder consultation exercise, and examples were provided of ways in which the legislation is or is not suitable at present. | Section 4.2.16 | Qualitative issue – no data collection possible.

Comparison of the EU position with other regions | The effects of EU rules on the position of animal pharmaceutical businesses | IFAH-Europe have commissioned research with businesses that seeks to estimate the issues associated with complying with legislation in Europe, the United States and Japan. | Section 2.3 | Primary research with companies in the United States and Japan in order to measure administrative burdens and compare to the EU position.

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*Note: The table above provides an overview of the data requirements, method of approach, and potential future data collection measures for assessing the impact of the revision of veterinary pharmaceutical legislation.*
### Database Details of data requirements Method of approach employed by this study Corresponding section(s) of the report Potential future data collection measures

<table>
<thead>
<tr>
<th>Database</th>
<th>Details of data requirements</th>
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<th>Corresponding section(s) of the report</th>
<th>Potential future data collection measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal framework tailored to the specific needs of the veterinary sector</td>
<td>Stakeholder views on the differences between the animal health and human health sectors, and identification of areas where there are variations and what they mean for the legislation</td>
<td>The differences between the animal health and human health sectors were investigated through the stakeholder consultation exercise. Examples where variations between the two sectors meant that a direct ‘copying’ of the human health legislation posed problems were identified (e.g. pharmacovigilance)</td>
<td>Example provided in Section 4.2.8</td>
<td>Qualitative issue – no data collection possible</td>
</tr>
<tr>
<td>Prices of veterinary medicinal products</td>
<td>Data on the prices of a selection of 3 veterinary medicinal products within 6 exemplar countries</td>
<td>Using the MA databases, 3 leading products were selected on the basis that they represented major product types and were authorised within the 6 case study countries. The 3 companies that owned the authorisations for these products were asked to submit data on their ‘list price’ (the price charged to wholesalers). Of these companies, 2 provided this information, but it has not been possible to present this data since the unit quantity was different in each country, thus preventing a comparison of prices between countries. Other prices (e.g. the prices charged by wholesalers and by veterinarians) are distorted by pricing systems including rebate and bulk-purchase schemes, and were thus omitted from the study. The pricing systems of veterinarians in particular are complex, and reflect issues such as the location of the veterinary practice and their balance of income between labour charges and the costs of medicines.</td>
<td>Not available</td>
<td>Primary research with companies</td>
</tr>
</tbody>
</table>
Annex 2 Standard Cost Model Methodology

This Annex provides further detail on the methodology employed in order to develop a Standard Cost Model (SCM) to measure the administrative burdens imposed on industry through the legislative framework for veterinary medicinal products. The results of the SCM are shown in Annex 7 and analysed in Section 2.3.

As discussed in Section 1.1.3, the data required in order to develop the SCM were collected through a combination of the business survey and analysis of data on MAs awarded through the various MA procedures. Note that it was initially intended to collect data on the number of actions per entity per year through the survey, but that the data that were returned were found to be weighted in favour of larger companies (which made up most of the survey responses). Consequently, the use of this survey data overestimates the overall level of activity carried out across the veterinary medicinal products industry. Instead, it was decided to use actual MA data obtained from the competent authorities to work out the number of MA applications submitted each year across the 30 EU/EEA countries.

The preliminary results of the SCM were reviewed and validated at an industry workshop attended by representatives from businesses that had responded to the survey (see Section 1.1.5 for details).

Table A2.2 The methodology employed to develop the SCM

<table>
<thead>
<tr>
<th>Variable</th>
<th>Sub-variable</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff tariff</td>
<td>CP, DCP, MRP</td>
<td>Businesses were asked to indicate their average hourly staff costs</td>
</tr>
<tr>
<td></td>
<td>NP</td>
<td>Respondents to the business survey were all based in Western Europe, primarily in high wage cost countries. The staff tariff in Eastern Europe is likely to be much lower, and so the average staff tariff through the National Procedure needs to be reduced (it is assumed that most activity through the CP, DCP and MRP involves businesses based in high wage cost countries). Data on product authorisations on national markets indicate that around 21% of all authorisations across the EU/EEA are within the NMS-10. Eurostat data on gross annual earnings indicates that average earnings in the NMS-10 are approximately 18% of average earnings in the EU-15(^1). The hourly staff tariff reported by businesses has thus been reduced by a factor of 17% (82% x 21%) to take account of the share of the activity through the National Procedure that takes place in Eastern Europe.</td>
</tr>
<tr>
<td>Number of actions per entity per year</td>
<td>CP</td>
<td>An estimate for the average number of MA applications (new, variation and renewal) submitted annually by an average business was obtained from data provided by the EMA, using an annual average over the period 2007-2009 (for new applications) and 1997-2009 (for variations and renewals).</td>
</tr>
<tr>
<td></td>
<td>DCP</td>
<td>An estimate for the average number of MA applications (new, variation and renewal) submitted annually by an average business was obtained from data provided by the HMA, using an annual average over the period 2005-2009.</td>
</tr>
<tr>
<td></td>
<td>MRP</td>
<td>An estimate for the average number of MA applications (new, variation and renewal) submitted annually by an average business was obtained from data provided by the HMA, using an annual average over the period 2005-2009.</td>
</tr>
<tr>
<td></td>
<td>NP</td>
<td>There is no single source of data on applications received by the competent authorities through the NP, and so it was instead necessary to generate an estimate of the volume of activity based on data obtained from the UK authorities (the only country for which data were available). Ratios were calculated between the average annual number of applications (new, renewal, variation) per IO and the average number of staff hours per INO.</td>
</tr>
</tbody>
</table>

variable and renewal) received by the UK authorities (2000-2009), and the 2010 figure for the number of authorised products on the UK market. These ratios were then applied to the figures for the number of authorised products on each national market (for the 19 countries that were available). For the remaining 11 EU/EEA countries for which no data on authorised products were available, the ratios were applied to an average of the number of authorised products per country for the 19 countries. The results were summed in each case to provide a estimate for the total number of applications received each year through the NP across the 30 EU/EEA countries. Note that the UK did not provide any data on Type IA variations, and so data on Type IB variations received has been used instead.

Finally, it was necessary to deflate the results in order to take account of the fact that many MA holders on national markets should be considered ‘inactive’ – they may hold one or more MAs, but in reality have not submitted applications in recent years. Not to do so would in effect overestimate the volume of activity submitted across the EU/EEA through the NP. The proportion of MA holders who could be considered inactive was estimated using UK data on applications received through the NP, where if no application was received by the authorities between 2000-2009, the MA holder was considered inactive. The resultant ‘deflators’ used were as follows: applications for new MAs reduced to 35% of the initial estimate; applications for Type 1A and 1B variations reduced to 49% of the initial estimate; applications for Type 2 variations reduced to 56% of the initial estimate; and pharmacovigilance activity reduced to 78% of the initial estimate.

Pharmacovigilance  There is no source of data on the number of pharmacovigilance records received by the competent authorities, and so this has been estimated. First, a ratio was calculated between the number of reports submitted each year by businesses (as reported in the business survey) and the number of products for which they had an MA (as reported in the business survey), in order to estimate the average number of pharmacovigilance reports submitted per product. On average, companies reported that, for each authorised product that they held, they submitted 0.42 adverse reaction reports, 0.46 serious/human adverse reaction reports, and 0.53 PSURs each year. These figures were then multiplied by data on the number of MAs held by each business (obtained from data on national MAs).

Packaging & labelling  There was no source of data on the number of units packaged and labelled by companies, so this has had to be estimated. Data were available from the competent authorities in Belgium as to the estimated volume of sales in 2010. The ratio between the number of units sold and the number of authorised products was calculated, and extrapolated to all 30 EU/EEA countries to produce an estimate for the total volume of sales. This figure was then divided by the estimated number of MA holders in the EU/EEA (594 companies) to produce an estimate for the number of sales per company.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Sub-variable</th>
<th>Methodology</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>variation and renewal) received by the UK authorities (2000-2009), and the 2010 figure for the number of authorised products on the UK market. These ratios were then applied to the figures for the number of authorised products on each national market (for the 19 countries that were available). For the remaining 11 EU/EEA countries for which no data on authorised products were available, the ratios were applied to an average of the number of authorised products per country for the 19 countries. The results were summed in each case to provide a estimate for the total number of applications received each year through the NP across the 30 EU/EEA countries. Note that the UK did not provide any data on Type IA variations, and so data on Type IB variations received has been used instead. Finally, it was necessary to deflate the results in order to take account of the fact that many MA holders on national markets should be considered ‘inactive’ – they may hold one or more MAs, but in reality have not submitted applications in recent years. Not to do so would in effect overestimate the volume of activity submitted across the EU/EEA through the NP. The proportion of MA holders who could be considered inactive was estimated using UK data on applications received through the NP, where if no application was received by the authorities between 2000-2009, the MA holder was considered inactive. The resultant ‘deflators’ used were as follows: applications for new MAs reduced to 35% of the initial estimate; applications for Type 1A and 1B variations reduced to 49% of the initial estimate; applications for Type 2 variations reduced to 56% of the initial estimate; and pharmacovigilance activity reduced to 78% of the initial estimate.</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td></td>
<td>There is no source of data on the number of pharmacovigilance records received by the competent authorities, and so this has been estimated. First, a ratio was calculated between the number of reports submitted each year by businesses (as reported in the business survey) and the number of products for which they had an MA (as reported in the business survey), in order to estimate the average number of pharmacovigilance reports submitted per product. On average, companies reported that, for each authorised product that they held, they submitted 0.42 adverse reaction reports, 0.46 serious/human adverse reaction reports, and 0.53 PSURs each year. These figures were then multiplied by data on the number of MAs held by each business (obtained from data on national MAs).</td>
</tr>
<tr>
<td>Packaging &amp; labelling</td>
<td></td>
<td>There was no source of data on the number of units packaged and labelled by companies, so this has had to be estimated. Data were available from the competent authorities in Belgium as to the estimated volume of sales in 2010. The ratio between the number of units sold and the number of authorised products was calculated, and extrapolated to all 30 EU/EEA countries to produce an estimate for the total volume of sales. This figure was then divided by the estimated number of MA holders in the EU/EEA (594 companies) to produce an estimate for the number of sales per company.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Staff costs per action</th>
<th>All</th>
<th>Staff time multiplied by staff tariff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff costs per entity per year</td>
<td>All</td>
<td>Staff costs per action multiplied by the number of actions per entity per year</td>
</tr>
<tr>
<td>Equipment costs per action</td>
<td>All</td>
<td>Businesses were asked to indicate the average equipment costs per action. Note that in many cases there were insufficient answers provided to enable a robust average figure to be obtained; in such cases we have assumed that equipment costs are zero.</td>
</tr>
<tr>
<td>Equipment costs per entity per year</td>
<td>All</td>
<td>Where available, equipment costs per action were multiplied by the number of actions per entity per year</td>
</tr>
<tr>
<td>Variable</td>
<td>Sub-variable</td>
<td>Methodology</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>--------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Outsourcing costs per action</td>
<td>All</td>
<td>Businesses were asked to indicate the average outsourcing costs per action.</td>
</tr>
<tr>
<td>Outsourcing costs per entity per year</td>
<td>All</td>
<td>Outsourcing costs per action multiplied by the number of actions per entity per year.</td>
</tr>
<tr>
<td>Number of entities</td>
<td>CP</td>
<td>The number of businesses to have used the CP was obtained from data provided by the EMA on the number of applications (any type) submitted through the CP for the period 1997-2009.</td>
</tr>
<tr>
<td></td>
<td>DCP</td>
<td>The number of businesses to have used the DCP was obtained from data provided by the HMA on the number of applications (any type) submitted through the DCP for the period 2005-2009.</td>
</tr>
<tr>
<td></td>
<td>MRP</td>
<td>The number of businesses to have used the MRP was obtained from data provided by the HMA on the number of applications (any type) submitted through the MRP for the period 2005-2009.</td>
</tr>
<tr>
<td></td>
<td>NP</td>
<td>Assumed to be equal to the total number of MA holders in the EU/EEA, estimated to be 594 businesses based on an extrapolation of MA data provided by the competent authorities.</td>
</tr>
<tr>
<td></td>
<td>Pharma-covigilance</td>
<td>Assumed to be equal to the total number of MA holders in the EU/EEA, estimated to be 594 businesses based on an extrapolation of MA data provided by the competent authorities.</td>
</tr>
<tr>
<td></td>
<td>Packaging &amp; labelling</td>
<td>Assumed to be equal to the total number of MA holders in the EU/EEA, estimated to be 594 businesses based on an extrapolation of MA data provided by the competent authorities.</td>
</tr>
<tr>
<td>Number of actions per year</td>
<td>All</td>
<td>Number of actions per entity per year multiplied by the number of entities. Note that this is not a requirement of the SCM, but can be used to validate the results of the model through comparison to actual data recorded by the competent authorities.</td>
</tr>
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</table>
Annex 3  Overview of National Datasets on Authorised Products

This Annex provides an overview of the contents of the databases of product authorisations provided by national competent authorities. In each case, data were requested in an excel format providing information on: product name; MA procedure; date MA was issued; ATCvet code of the product; target species; and the identity of the MA holder. Table A3.3 below provides a summary of the responses.

Table A3.3  Details of the contents of product authorisation databases provided by national competent authorities

<table>
<thead>
<tr>
<th>Country</th>
<th>Response</th>
<th>Product name</th>
<th>MA procedure</th>
<th>Date of MA</th>
<th>ATCvet code</th>
<th>Target species</th>
<th>MA Holder</th>
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<td>AT</td>
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</tr>
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<td>Yes</td>
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<tr>
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<td>PL</td>
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<tr>
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</tr>
<tr>
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<td>Yes</td>
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</tr>
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<tr>
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<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
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</tr>
<tr>
<td>UK</td>
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<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Total</td>
<td>19</td>
<td>19</td>
<td>19</td>
<td>15</td>
<td>15</td>
<td>15</td>
<td>19</td>
</tr>
</tbody>
</table>
## Annex 4  Key to the ATCvet Classification System

Table A4.4  The ATCvet classification system

<table>
<thead>
<tr>
<th>ATCvet 1st tier category</th>
<th>Description of contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>QA</td>
<td>Preparations used for the treatment of diseases affecting the alimentary tract or metabolism (e.g. antacids and antiemetics), as well as antispasmodic and anticholinergic agents, vitamins and drugs used in diabetes.</td>
</tr>
<tr>
<td>QB</td>
<td>Preparations mainly affecting the blood or the blood forming organs (e.g. antithrombotic agents, antianemic preparations and plasma substitutes)</td>
</tr>
<tr>
<td>QC</td>
<td>Preparations used in the treatment of diseases affecting the cardiovascular system, or whose action is believed to be mediated mainly via the cardiovascular system (e.g. antihypertensives and drugs for cardiac diseases).</td>
</tr>
<tr>
<td>QD</td>
<td>Dermatological preparations, mostly for topical use (e.g. antifungals, antibiotics, corticosteroids and antiseptics for topical use).</td>
</tr>
<tr>
<td>QG</td>
<td>Gynaecological antiinfectives and antisepsics for local and intravaginal/ intrauterine use (e.g. urologicals and hormonal contraceptives).</td>
</tr>
<tr>
<td>QH</td>
<td>Hormonal preparations for systemic use, excluding sex hormones and insulins (e.g. pancreatic hormones).</td>
</tr>
<tr>
<td>QI</td>
<td>Immunologicals for veterinary use (e.g. vaccines, immune sera and immunoglobulins).</td>
</tr>
<tr>
<td>QJ</td>
<td>Antinfectives, antibacterials and antimycobacterials for systemic and intramammary use.</td>
</tr>
<tr>
<td>QL</td>
<td>Preparations, used in the treatment of malignant neoplastic diseases (e.g. alkylating agents, antimetabolites, plant alkaloids and cytotoxic antibiotics)</td>
</tr>
<tr>
<td>QM</td>
<td>Preparations used for the treatment of disease in or symptoms of the musculo-skeletal system (e.g. antiinflammatory agents).</td>
</tr>
<tr>
<td>QN</td>
<td>Preparations affecting the nervous system, both centrally and peripherally (e.g. antidepressants and antipsychotics).</td>
</tr>
<tr>
<td>QP</td>
<td>Antiparasitic preparations, including antiprotozoals, insecticides and repellents for local and systemic use.</td>
</tr>
<tr>
<td>QR</td>
<td>Preparations for the treatment of diseases in the respiratory system – i.e. the nose, throat and lungs (e.g. cough suppressants).</td>
</tr>
<tr>
<td>QS</td>
<td>Preparations for topical treatment of diseases in the sensory organs – i.e. the eyes and the ears (e.g. ophtalmologicals).</td>
</tr>
<tr>
<td>QV</td>
<td>Preparations that cannot be classified in any other anatomical main group, including medical devices or general nutrients.</td>
</tr>
</tbody>
</table>
Annex 5 Analysis of National MA Databases

This Annex reviews data on the number of veterinary medicinal products with marketing authorisation in the European Union (EU) and European Economic Area (EEA).

Data were requested from the competent authorities in each of the 30 EU/EEA countries. A total of 19 compatible responses were received. An additional six responses were received but could not be used since data were either incomplete or could not be extracted in a way which would enable analysis (e.g. because they consisted of a series of PDF files of the Summary of Product Characteristics (SPC) files). Liechtenstein advised that it follows Switzerland and maintains no separate authorisation registry. The content of datasets received from competent authorities varied, and a summary of the content of national MA databases is provided in Annex 3. The coverage of the data supplied affects the extent to which particular questions can be answered.

The data provided were as of May 2010.

A5.1 Total Numbers of Authorised Products

This sub-section analyses data on the number of authorised products on each of the national markets for which data were available. In order to provide an alternative assessment of the number of authorised products, therefore, lists of MAs in each of the countries have been consolidated according to product brand names. This is because there are differences in the way in which countries record MAs, such that the same product may be registered as one authorisation in one country, but as two or more authorisations in another (e.g. differentiated by dosage, with a 50 milligram and 250 milligram package of the same product being recorded as separate authorisations). The impact of these differences is to inflate the total number of apparent product authorisations in countries where multiple sub-divisions are the norm.

Figure A5.1 shows the unadjusted figures, with one entry for each separate authorisation recorded. Figure A5.2 gives the adjusted numbers, with one entry for each product 'brand'.

42 'Brand' here is used to signify an individual product name. For example, in the UK there are 8 distinct authorisations for the product 'Advantage', differentiated by the species (cats or dogs), the animal size (small or large), and the dosage. For the purposes of analysis of product brands, these 8 authorisations are reduced to a single record for the brand 'Advantage'.
There was considerable variation between countries in terms of the number of MAs - from 311 products in Malta through to 2,944 products in France. The number of MAs on national markets (as at May 2010)

Source: GHK analysis of MA databases

The number of authorised product brands on national markets also varied significantly (France had the most); comparison with other countries highlights the differences in the way that countries record product authorisations (e.g. Belgium and Norway, both of which had considerably fewer authorised product brands).

The number of authorised product brands on national markets (as at May 2010)

Source: GHK analysis of MA databases

There follows an analysis of the number of MAs targeted at selected animal populations. Figure A5.3 plots the number of MAs targeted at cattle against cattle populations, Figure A5.4 provides the same data for pigs, Figure A5.5 for sheep and Figure A5.6 for goats. Note that the data provided here are actual animal populations, whereas the analysis presented in
Figure 2.5 showed Livestock Units (LSU), which enable multiple animal species to be ‘aggregated’ into a single figure (see Section 2.1.1 for more details).

Figure A5.3 Countries with the fewest cattle also had the smallest numbers of products authorised for use with cattle

The cattle population (1000 heads of cattle) (2009), and the number of MAs for products targeted at cattle (as at May 2010)

Source: GHK analysis of MA databases; Eurostat (apro_mt_ls)

Figure A5.4 Countries with fewer pigs also had smaller numbers of products authorised for use with pigs, though the relationship between the two variables was not as clear as it was for cattle

The pig population (1000 heads of pigs) (2009), and the number of MAs for products targeted at pigs (as at May 2010)

Source: GHK analysis of MA databases; Eurostat (apro_mt_ls)

http://epp.eurostat.ec.europa.eu/portal/page/portal/agriculture/data/database
Figure A5.5 Overall, countries with the fewest numbers of sheep also had the smallest numbers of products authorised for use with sheep, though again the relationship between the two variables was not always clear (e.g. the United Kingdom has fewer products authorised for use with sheep than either Romania or France, despite having more than double the number of sheep than either country).

*The sheep population (1000 heads of sheep) (2009), and the number of MAs for products targeted at sheep (as at May 2010)*

Source: GHK analysis of MA databases; Eurostat (apro_mt_ls)

Figure A5.6 Countries with the fewest goats also had the smallest numbers of products authorised for use with goats.

*The goat population (1000 heads of goats) (2009), and the number of MAs for products targeted at goats (as at May 2010)*

Source: GHK analysis of MA databases; Eurostat (apro_mt_ls)
A5.2 Marketing Authorisation Procedure

National MA databases included information on the MA route followed for each authorisation (summarised in Figure A5.7).

The authorisation channels available are:

- National procedure (NP);
- Centralised procedures (CP);
- Decentralised procedure (DCP); and
- Mutual recognition procedure (MRP).

In almost all countries, the majority of products had been authorised through the national procedure (particularly in France and the Czech Republic) (Figure A5.7). Smaller markets (notably Malta and Norway) had higher proportions of products authorised through the centralised procedure (though there are variations in the actual numbers of CP products recorded in the national databases as a result of differences in approach to recording authorisations). Larger countries had higher numbers of products authorised through the mutual recognition procedure or decentralised procedure (Malta has just 1 product authorised through the DCP).

Figure A5.7 Most marketing authorisations have been awarded through national procedures

The MA procedure followed for all authorised products on national markets (as at May 2010)

Source: GHK analysis of MA databases
A5.3 Therapeutic Categories of MAs

Moving beyond the overall population of MAs it is possible to explore patterns in the types of veterinary medicines authorised in the EU and EEA by examining the information available on the therapeutic class of products. Data on the therapeutic categories of MAs were included in 15 of the 19 national product databases.

For this analysis therapeutic categories have been derived from the Anatomical Therapeutic Chemical (ATC) classification system, which was introduced for veterinary medicinal products in 1990. Under this system, products are categorised according to their therapeutic use, starting with 15 anatomical groups labelled QA to QV (an overview is provided in Table A4.4 in Annex 4). This first tier category is followed by a numerical second tier based on the main therapeutic groups. For the purposes of the analysis presented in this Annex, only the first tier of categorisation has been used. The ATCvet categories of MAs in each of the countries are shown in Figure A5.8.

Figure A5.8 On average, ATCvet categories QJ (antiinfectives), QP (antiparasitics) and QI (immunologicals) accounted for the largest numbers of MAs.

Source: GHK analysis of MA databases

---

A5.4 Target Species of Authorised Products

The availability of authorised medicines for particular species is a key part of the availability ‘problem’ that forms the context to this study and the Commission’s consideration of changes to the EU legislative framework for veterinary medicines. Figure A5.9 presents data on the total number of MAs targeted at each of the 11 priority species. All other animal species have been grouped into an ‘other’ category, which includes the likes of rabbits, ducks, geese, and other companion animals.

**Figure A5.9** More products are authorised for dogs than any other species

Source: GHK analysis of MA databases

Analysis by species is presented in Sections A5.4.2 to A5.4.12 below, for all countries for which data were available and using the ATCvet classification system.
### A5.4.2 Dogs

The therapeutic categories of all of the MAs targeted at dogs are shown in Figure A5.10.

**Figure A5.10** On average, the ATCvet category QP (antiparasitics) was the most common type of MA targeted at dogs, followed by QJ (antiinfectives)

*Therapeutic categories (ATCvet system) for all MAs on national markets targeted at dogs (as at May 2010)*

![Graph showing the distribution of therapeutic categories for dogs](image_url)

*Source: GHK analysis of MA databases*
A5.4.3 Cats

The therapeutic categories of the MAs targeted at cats are shown in Figure A5.11.

Figure A5.11 On average, antiparasitics (QP) and antiinfectives (QJ) were the most common types of MA targeted at cats.

Source: GHK analysis of MA databases
A5.4.4 Cattle

The therapeutic categories of all of the MAs targeted at cattle are shown in Figure A5.12.

Figure A5.12 On average, the ATCvet category QJ (antiinfectives) was by some margin the most common type of product targeted at cattle

Therapeutic categories (ATCvet system) for all MAs on national markets targeted at cattle (as at May 2010)

Source: GHK analysis of MA databases
A5.4.5 Horses

The therapeutic categories of MAs targeted at horses are shown in Figure A5.13.

Figure A5.13 The distribution of the therapeutic categories across MAs targeted at horses was more diverse than for many other species, with antiparasitics (QP), musculo-skeletal (QM), nervous system (QN), antiinfectives (QJ) and immunological (QI) products on average accounting for approximately the same number of MAs.

Therapeutic categories (ATCvet system) for all MAs on national markets targeted at horses (as at May 2010)

Source: GHK analysis of MA databases
A5.4.6 Pigs

The therapeutic categories of all of the MAs targeted at pigs are shown in Figure A5.14.

Figure A5.14 Antiinfectives (QJ) on average accounted for around half of all MAs. Immunologicals (QI) also accounted for a significant proportion of MAs targeted at pigs.

Therapeutic categories (ATCvet system) for all MAs on national markets targeted at pigs (as at May 2010)

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Source: GHK analysis of MA databases
A5.4.7 Sheep

The therapeutic categories of all of the MAs targeted at sheep are shown in Figure A5.15. Antiinfectives (QN) and antiparasitics (QP) were the most common type of product authorised for use with sheep, followed by products targeting the alimentary tract/metabolism (QA).

Therapeutic categories (ATCvet system) for all MAs on national markets targeted at sheep (as at May 2010)

Source: GHK analysis of MA databases
A5.4.8 Goats

For all of the countries for which data were available, the therapeutic categories (using the ATCvet classification system) of all of the MAs targeted at goats is shown in Figure A5.16.

Figure A5.16 Overall there were relatively few authorised products targeted at goats in the countries for which data on therapeutic categories were also available (only Germany, the Czech Republic, Lithuania and the Netherlands had over 50 products authorised for use with goats)

Therapeutic categories (ATCvet system) for all MAs on national markets targeted at goats (as at May 2010)

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Source: GHK analysis of MA databases
A5.4.9 Chickens

For all of the countries for which data were available, the therapeutic categories (using the ATCvet classification system) of all of the MAs targeted at chickens is shown in Figure A5.17.

Figure A5.17 For products intended for use with chickens, ATCvet code QI (immunologicals) was the most common therapeutic category, the only species category for which this was the case. ATCvet code QJ (antiinfectives) was also common amongst authorised products targeted at chickens, though in Finland and Malta there were very few of these types of product authorised.

Therapeutic categories (ATCvet system) for all MAs on national markets targeted at chickens (as at May 2010)

Source: GHK analysis of MA databases
### A5.4.10 Turkeys

The therapeutic categories of the MAs targeted at turkeys are shown in Figure A5.18. These data should be treated with particular caution since it was not always clear from national datasets whether the competent authorities had accounted for turkeys separately within their classification systems (Figure A5.18 indicates that zero products were authorised for use with turkeys in Denmark or Belgium).

#### Figure A5.18

Antiinfectives (QJ) were the type of product most commonly authorised for turkeys, followed by followed by immunologicals (QI) and, in most countries products targeting the alimentary tract/ metabolism (QA)

*Therapeutic categories (ATCvet system) for all MAs on national markets targeted at turkeys (as at May 2010)*

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*Source: GHK analysis of MA databases*
A5.4.11 Bees

The therapeutic categories of the MAs targeted at bees are shown in Figure A5.19.

Figure A5.19 Very few authorised products were targeted at bees (from zero in Finland to five in Cyprus and the UK). In some cases data on the ATCvet code were not available, but where they were, all products were categorised as QP (antiparasitics)

*Therapeutic categories (ATCvet system) for all MAs on national markets targeted at bees (as at May 2010)*

Source: GHK analysis of MA databases
A5.4.12  Salmon, Trout and Other Fish

The therapeutic categories of the MAs targeted at salmon, trout and other fish are shown in Figure A5.20.

Figure A5.20  Relatively few authorised products were targeted at salmon, trout and other fish on any national market - from zero in Lithuania and the Netherlands to 29 in the UK. Most were immunologicals (QI).

**Therapeutic categories (ATCvet system) for all MAs on national markets targeted at salmon, trout and other fish (as at May 2010)**

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<td>0</td>
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<td>1</td>
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<td>0</td>
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<td>QC</td>
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<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Source: GHK analysis of MA databases
Annex 6 Analysis of Marketing Authorisation Applications

This Annex presents analysis of MA applications received by the competent authorities through the four authorisation procedures. Applications include:

- Applications for a new MA or for the renewal of an existing authorisation; and,
- Variations or extensions to existing MA, disaggregated by type (IA, IB, and II)\(^{45}\).

The section commences with a review of data on applications received by the EMA through the Centralised Procedure, then analyses applications received by national competent authorities through either the MRP or DCP, then finally analyses the applications received by the UK authorities through the National Procedure (the UK was the only competent authority that provided these data).

A6.1 Applications processed through the Centralised Procedure

The European Medicines Agency (EMA) provided information on the number of applications received for processing via the Centralised Procedure between 1997 and 2009. The dataset provided includes Type I variations until 2003, after which they were divided into Type IA and IB variations.

A6.1.1 Number of applications received via the Centralised Procedure

Figure A6.21 shows the total number of applications received by the EMA through the Centralised Procedure between 1997 and 2009.

The most common form of Centralised Procedure application was for a Type II variation to an existing MA: 214 of these were submitted to the EMA between 1997-2009. Just 73 MA renewal applications were received over the 12 year period 1997-2009.

\[ \text{The number of applications received through the Centralised Procedure, by type of application (1997-2009)} \]

<table>
<thead>
<tr>
<th>Type I Variation (to 2003)</th>
<th>Type IA Variation (2003-2009)</th>
<th>Type IB Variation (2003-2009)</th>
<th>Type II Variation</th>
<th>Extension</th>
<th>MA Renewal</th>
<th>New MA</th>
</tr>
</thead>
<tbody>
<tr>
<td>153</td>
<td>155</td>
<td>217</td>
<td>264</td>
<td>60</td>
<td>86</td>
<td>145</td>
</tr>
</tbody>
</table>

Source: GHK analysis of MA databases

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\(^{45}\) Type IA and Type IB variations are the least complex, and generally cover administrative changes such as an amendment to the identity or contact details of the manufacturer. Type II variations are more complex than Type I variations, and generally cover changes to the manufacturing process or the Summary of Product Characteristics.
Applications per year via the Centralised Procedure

Figure A6.22 shows the annual number of applications received by the EMA for processing under the Centralised Procedure between 1997 and 2009.

The total number of applications received by the EMA through the centralised procedure has risen steadily (from 8 in 1997 to 168 in 2009); the number of Type II variation applications has increased from 13-19 a year in 2001-2005 to 47 in 2007 and 52 in 2008.

The number of applications received each year (1997-2009), by type of application

<table>
<thead>
<tr>
<th>Year</th>
<th>New MA</th>
<th>MA Renewal</th>
<th>Extension</th>
<th>Type II Variation</th>
<th>Type IB Variation (2003-2009)</th>
<th>Type IA Variation (2003-2009)</th>
<th>Type I Variation (to 2003)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
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<tr>
<td>1998</td>
<td>13</td>
<td>0</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>1999</td>
<td>5</td>
<td>0</td>
<td>5</td>
<td>18</td>
<td>0</td>
<td>0</td>
<td>17</td>
</tr>
<tr>
<td>2000</td>
<td>7</td>
<td>0</td>
<td>5</td>
<td>13</td>
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<td>0</td>
<td>5</td>
<td>13</td>
<td>7</td>
<td>4</td>
<td>32</td>
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<tr>
<td>2002</td>
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<td>0</td>
<td>2</td>
<td>18</td>
<td>35</td>
<td>12</td>
<td>17</td>
</tr>
<tr>
<td>2003</td>
<td>3</td>
<td>0</td>
<td>2</td>
<td>13</td>
<td>36</td>
<td>14</td>
<td>30</td>
</tr>
<tr>
<td>2004</td>
<td>11</td>
<td>0</td>
<td>3</td>
<td>18</td>
<td>26</td>
<td>18</td>
<td>23</td>
</tr>
<tr>
<td>2005</td>
<td>8</td>
<td>2</td>
<td>3</td>
<td>19</td>
<td>47</td>
<td>19</td>
<td>33</td>
</tr>
<tr>
<td>2006</td>
<td>16</td>
<td>16</td>
<td>0</td>
<td>19</td>
<td>52</td>
<td>19</td>
<td>26</td>
</tr>
<tr>
<td>2007</td>
<td>14</td>
<td>10</td>
<td>9</td>
<td>25</td>
<td>40</td>
<td>25</td>
<td>30</td>
</tr>
<tr>
<td>2008</td>
<td>15</td>
<td>22</td>
<td>4</td>
<td>47</td>
<td>35</td>
<td>25</td>
<td>46</td>
</tr>
<tr>
<td>2009</td>
<td>15</td>
<td>27</td>
<td>3</td>
<td>52</td>
<td>32</td>
<td>19</td>
<td>25</td>
</tr>
</tbody>
</table>

Source: GHK analysis of MA databases
A6.1.2 Target species of applications via the Centralised Procedure

The target species of the products involved in applications through the Centralised Procedure between 1997 and 2009 is shown in Figure A6.23:

Figure A6.23 Products targeted at dogs accounted for the largest number of applications (364 in all), followed by cats, then pigs, cattle and horses – none of the applications processed through the Centralised Procedure were targeted at goats, bees or salmon, trout and other fish, whilst just 2 applications concerned products for use with sheep.

Target species of the products that applications through the Centralised Procedure concerned, by type of application (1997-2009)

Source: GHK analysis of MA databases
A6.1.3 Therapeutic category of applications via the Centralised Procedure

Figure A6.24 shows the number of applications received by the EMA through the Centralised Procedure (1997-2009), disaggregated by the ATCvet category of the products (see Annex 4).

Figure A6.24 Immunologicals (ATCvet category QI) accounted for more Centralised Procedure applications than any other type of product (246 in total), followed by musculo-skeletal products and anti-infectives. Almost half of the immunological applications were Type II variations.

ATCvet code of the products that applications through the Centralised Procedure concerned, by type of application (1997-2009)

Source: GHK analysis of MA databases
A6.1.4 Time elapsed between receipt and determination of applications via the Centralised Procedure

Data are available on the number of days elapsed between the receipt and the determination of an application. This period includes time during which the ‘clock stopped’ (e.g. where the applicant was responding to a request from the competent authorities). The results are shown in Figure A6.25. Of the three types of variation, Type IA variations were approved the quickest (at an average of 58 days compared to an average of 153 days for Type II variations).

Figure A6.25 On average, applications for the new MAs took 536 days from receipt to determination

Source: GHK analysis of MA databases
A6.2 Applications Processed Through the Mutual Recognition Procedure

The Heads of Medicines Agency (HMA) provided data on marketing authorisation applications received through the Mutual Recognition Procedure (MRP). These data covered applications for new MAs, line extensions\(^{46}\), variations, and renewals received between 2006 and 2009. Data on the year in which applications were received were not available for MA renewals and variations.

A6.2.1 Number of applications received via the Mutual Recognition Procedure

Figure A6.26 shows the total number of applications received by competent authorities through the MRP between 2006 and 2009.

Figure A6.26 2,235 applications were received through the MRP between 2006 and 2009, of which 330 (15 per cent) concerned new MAs or line extensions. Of the variations submitted, Type IA variations were the most common, with 628 received between 2006 and 2009.

The number of applications received through the MRP, by type of application (2006-2009)

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>Number of Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>New MA, Line Extension</td>
<td>330</td>
</tr>
<tr>
<td>MA Renewal</td>
<td>309</td>
</tr>
<tr>
<td>Type IA Variation</td>
<td>628</td>
</tr>
<tr>
<td>Type IB Variation</td>
<td>420</td>
</tr>
<tr>
<td>Type II Variation</td>
<td>534</td>
</tr>
<tr>
<td>No data</td>
<td>14</td>
</tr>
</tbody>
</table>

Source: GHK analysis of MA databases

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\(^{46}\) Line extensions are more significant in scope than variations and cover changes to active ingredients, pharmaceutical form or the route of administration. Extensions also include the addition of a new food-producing species to the market authorisation.
A6.2.2 Applications per year via the Mutual Recognition Procedure

Data on the year in which applications were received were only available in respect of applications for a new MA or a line extension (Figure A6.27).

Figure A6.27 The number of applications for new MAs or line extensions received each year through the MRP declined steadily between 2006 and 2009.

The number of applications for new MAs or line extensions that were received by the competent authorities through the MRP, by year (2006-2009)

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
<td>98</td>
</tr>
<tr>
<td>2007</td>
<td>89</td>
</tr>
<tr>
<td>2008</td>
<td>84</td>
</tr>
<tr>
<td>2009</td>
<td>59</td>
</tr>
</tbody>
</table>

Source: GHK analysis of MA databases
A6.2.3 The role of the competent authorities via the Mutual Recognition Procedure

For new applications/line extensions submitted through the MRP between 2006 and 2009, data were available on the role of the Member States for each application (i.e., whether they were a Reference Member State (RMS) or Concerned Member State (CMS))\(^{47}\). These data thus show the extent to which RMS responsibility (which is time and resource consuming) was distributed across competent authorities, and also which countries performed the CMS role (a requirement if the product is to receive authorisations, and thus an indicator of the geographical extent of new product authorisations). The results are shown in Figure A6.28.

Figure A6.28 The RMS role has generally been taken by the UK, Ireland, France, Germany or Spain. Other countries were rarely the RMS but frequently a CMS (e.g., Italy, Portugal and Belgium). Countries such as Malta, Iceland, Bulgaria and Romania have rarely performed the CMS role, indicating that applications for new MAs through the MRP often excluded these countries (thus affecting product availability).

The RMS and CMS for the applications for new MAs/line extensions received through the MRP (2006-2009)

\(^{47}\) Under the MRP, the RMS is the Member State that has already authorised the product; the RMS submits their evaluation of the product to the other Member States (CMSs), who are asked to mutually recognise the MA of the RMS.

Source: GHK analysis of MA databases
A6.2.4 Target species of applications via the Mutual Recognition Procedure

Figure A6.29 shows the number of applications received by the competent authorities through the MRP between 2006-2009, disaggregated by the target species of the products.

Figure A6.29 Dogs were the most common target species for applications submitted via the MRP (with 842 applications in total), followed by cattle (535), pigs (389) and chickens (233); applications for new MAs or line extensions formed a large proportion of applications for products targeted at goats and salmon, trout and other fish.

Target species of the products that applications through the MRP concerned, by type of application (2006-2009)

Source: GHK analysis of MA databases
Figure A6.30 shows the number of applications received by the competent authorities through the MRP between 2006-2009, according to the ATCvet code (see Annex 4) of the product.

Figure A6.30 Antiparasitic (QP) and immunological (QI) products accounted for the largest number of applications submitted through the MRP, followed by antiinfectives (QJ). Immunologicals accounted for the largest number of applications for new MAs or line extensions (89 applications), suggesting a higher level of new product innovation in this area than others.

ATCvet code of the products that applications through the MRP concerned, by type of application (2006-2009)

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>QA</th>
<th>QB</th>
<th>QC</th>
<th>QD</th>
<th>QG</th>
<th>QH</th>
<th>QI</th>
<th>QJ</th>
<th>QL</th>
<th>QM</th>
<th>QN</th>
<th>QP</th>
<th>QR</th>
<th>QS</th>
<th>QV</th>
<th>No data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type II Variation</td>
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<td>33</td>
<td>1</td>
<td>14</td>
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<td>232</td>
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<td>18</td>
<td>11</td>
<td>115</td>
<td>0</td>
<td>5</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>Type IB Variation</td>
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<td>39</td>
<td>0</td>
<td>13</td>
<td>19</td>
<td>85</td>
<td>68</td>
<td>4</td>
<td>19</td>
<td>3</td>
<td>153</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Type IA Variation</td>
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<td>71</td>
<td>3</td>
<td>21</td>
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<td>195</td>
<td>3</td>
<td>6</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>MA Renewal</td>
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<td>18</td>
<td>1</td>
<td>13</td>
<td>5</td>
<td>79</td>
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<td>93</td>
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<td>3</td>
</tr>
<tr>
<td>New MA, Line Extension</td>
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<td>3</td>
<td>10</td>
<td>5</td>
<td>22</td>
<td>3</td>
<td>89</td>
<td>57</td>
<td>6</td>
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<td>19</td>
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<td>0</td>
<td>16</td>
</tr>
</tbody>
</table>

Source: GHK analysis of MA databases
A6.3 Applications processed through the Decentralised Procedure

The HMA provided data on Marketing Authorisation applications received through the decentralised procedure (DCP). These data covered applications for new MAs, line extensions, variations, and renewals received between 2006 and 2009. Data on the years in which applications were received were not available for MA renewals and variations.

A6.3.1 Number of applications received through the Decentralised Procedure

Figure A6.31 shows the total number of applications received by competent authorities through the DCP between 2006 and 2009.

Figure A6.31 597 applications were submitted through the DCP between 2006 and 2009, of which 210 applications concerned new MAs or line extensions. Of the variations, Type IB variations were the most common, with 162 applications received by the competent authorities.

The number of applications received by the competent authorities through the DCP, by type of application (2006-2009)

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>Number of Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>New MA, Line Extension</td>
<td>210</td>
</tr>
<tr>
<td>MA Renewal</td>
<td>18</td>
</tr>
<tr>
<td>Type IA Variation</td>
<td>109</td>
</tr>
<tr>
<td>Type IB Variation</td>
<td>162</td>
</tr>
<tr>
<td>Type II Variation</td>
<td>98</td>
</tr>
</tbody>
</table>

Source: GHK analysis of MA databases
A6.3.1 Applications per Year through the Decentralised Procedure

Data on the year that applications were received were only available in respect of applications for a new MA or a line extension (Figure A6.32).

Figure A6.32 Insufficient data are available on which to draw a comprehensive picture of the usage of the DCP over time (the DCP was only introduced in 2005)

The number of applications for new MAs or line extensions that were received by the competent authorities through the DCP, by year (2006-2009)

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2006</td>
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<tr>
<td>2007</td>
<td>94</td>
</tr>
<tr>
<td>2008</td>
<td>84</td>
</tr>
<tr>
<td>2009</td>
<td></td>
</tr>
</tbody>
</table>

Source: GHK analysis of MA databases
A6.3.2 The role of the competent authorities through the Decentralised Procedure

For new applications/line extensions submitted through the DCP between 2006 and 2009, data were available on the role of the Member States for each application (i.e., whether they were a Reference Member State (RMS) or Concerned Member State (CMS))\(^\text{48}\). The information on the identities of the CMS in particular gives an indication of the geographical scope of new applications for new MAs via the DCP. The results of the analysis undertaken are shown in Figure A6.33.

Figure A6.33 The role of RMS was concentrated within a small number of countries (the UK, then Ireland and France). Other countries were rarely the RMS but often a CMS (Spain, Italy and Portugal). Countries such as Malta, Iceland, Estonia, Cyprus, Slovenia and Lithuania have rarely been registered as a CMS, indicating that applications for new MAs through the DCP often excluded these countries (thus affecting product availability).

\[\text{The RMS and CMS for the applications for new MAs/line extensions received through the DCP (2006-2009)}\]

Source: GHK analysis of MA databases

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\(\text{48 Under the DCP, a Member State will be asked by a business to act as the RMS, and will carry out an initial evaluation of a product and issue a draft assessment report. The other Member States within which MA is sought – known as CMSs – then either agree with the RMS’s evaluation or they ask further questions/raise objections.}\)
A6.3.3 Target species of applications through the Decentralised Procedure

Figure A6.34 shows the number of applications received by the competent authorities through the DCP, disaggregated by the target species of the products.

Figure A6.34 Products targeted at dogs formed the majority of applications received through the DCP (297 applications in total), followed by pigs (135), cattle (124), and cats (101)

Target species of the products that applications through the DCP concerned, by type of application (2006-2009)

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>Dogs</th>
<th>Cats</th>
<th>Cattle</th>
<th>Horses</th>
<th>Pigs</th>
<th>Sheep</th>
<th>Goats</th>
<th>Chickens</th>
<th>Turkeys</th>
<th>Bees</th>
<th>Salmon, Trout, Other Fish</th>
</tr>
</thead>
<tbody>
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<td>2</td>
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</tr>
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<td>1</td>
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<td>6</td>
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<td>0</td>
</tr>
<tr>
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</tr>
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<td>MA Renewal</td>
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<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
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<td>21</td>
<td>72</td>
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<td>7</td>
<td>28</td>
<td>11</td>
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</tr>
</tbody>
</table>

Source: GHK analysis of MA databases
A6.3.4 Therapeutic category of applications through the Decentralised Procedure

Figure A6.35 shows the number of applications received by the competent authorities through the DCP between 2006 and 2009, disaggregated by the ATCvet code (see Annex 4) of the products.

Figure A6.35 Therapeutic category QJ (antiinfectives) accounted for the single largest number of applications submitted through the DCP, followed by QP (antiparasitics) then QI (immunologicals). For a number of ATCvet codes – notably QL (Antineoplastics), QR (respiratory), QB (blood/ blood organs) and QD (dermatologicals) – there were between zero and two applications submitted between 2006-2009

ATCvet code of the products that applications through the DCP concerned, by type of application (2006-2009)

Source: GHK analysis of MA databases
A6.4 Applications processed through the National Procedure

Data on MA applications received through the National Procedure were requested from the competent authorities in the Member States. Only the UK was able to provide the data within the research timescale. The data provided by the UK authorities covers the period 2000 to 2009, and shows applications received for: new MAs, MA renewals, Type IB variations, and Type II variations. No data were available on the number of Type IA variation applications received.

A6.4.1 Number of applications received through the National Procedure in the UK

Figure A6.36 shows the total number of applications received by the competent authority in the UK between 2000 and 2009.

Figure A6.36  The UK competent authority received 7,895 applications between 2000 and 2009, of which 7 per cent were applications for new MAs and 33 per cent applications for MA renewal. The majority (61 per cent) of applications received were for variations, with Type II variations forming the single largest proportion (39 per cent of all applications)

The number of applications received, by type of application (2000-2009)

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>Number of Applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>New MA</td>
<td>529</td>
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<tr>
<td>MA renewal</td>
<td>2,589</td>
</tr>
<tr>
<td>Type IB Variation</td>
<td>1,701</td>
</tr>
<tr>
<td>Type II Variation</td>
<td>3,076</td>
</tr>
</tbody>
</table>

Source: GHK analysis of MA databases
A6.4.2 Applications per year through the National Procedure in the UK

Figure A6.37 shows the number of MA applications received by the UK competent authority each year between 2000 and 2009.

Figure A6.37 The number of applications for new MAs received each year ranged from between 60 and 90 annually between 2000 and 2004, dropping to 21 in 2008, then zero in 2009; applications received for MA renewals ranged between 250 and 330 a year between 2000 and 2007, before declining to just 112 in 2009; the number of applications for variations increased significantly between 2005 and 2006, before decreasing between 2008 and 2009.

The number of applications received each year, by type of application (2000-2009)

Source: GHK analysis of MA databases
A6.4.3 Target species of applications through the National Procedure in the UK

Figure A6.38 shows the number of applications received by the UK competent authority, disaggregated by the target species of the products.

Figure A6.38 The largest numbers of applications for new MAs were received for products targeting dogs (231 applications in total), followed by cats (114) then cattle (106). High numbers of applications for variations were received for products targeting dogs, cats and cattle. Between 2000 and 2009, no applications were received by the UK authorities for new MAs for products targeting bees

Target species of the products that applications concerned, by type of application (2000-2009)

Source: GHK analysis of MA databases
A6.4.4 Therapeutic category of applications through the National Procedure in the UK

Figure A6.39 shows the number of applications received by the UK competent authority between 2000 and 2009, disaggregated by the ATCvet code (see Annex 4) of the products.

Figure A6.39 The most common ATCvet code of products was QP (antiparasitics), followed by QJ (antiinfectives) and QI (immunologicals). Just under half (46 per cent) of applications for new MAs were for products that were coded QP (antiparasitics). Overall, 7 per cent of applications were for new MAs

ATCvet code of the products that applications concerned, by type of application (2000-2009)

Source: GHK analysis of MA databases
A6.4.5 Time elapsed between receipt and determination of applications through the National Procedure in the UK

Data are available on the number of days that elapsed between the receipt and the determination of an application. This includes time during which the ‘clock stopped’ (e.g. where the applicant was responding to a request from the competent authority). The results are shown in Figure A6.40.

Figure A6.40 Applications for new MAs took 371 days from receipt to determination, whilst renewals took longer (an average of 409 days). Of the two types of variation, Type IB variations took the least number of days to determine (101 days on average), compared to an average of 174 days for Type II variations.

Average number of days elapsed between receipt and determination of applications, by type of application (2000-2009)

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<th>Average Days Elapsed</th>
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<td>MA renewal</td>
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<td>Type IB Variation</td>
<td>102</td>
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<tr>
<td>Type II Variation</td>
<td>175</td>
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</table>

Source: GHK analysis of MA databases
A6.4.6 Outcome of applications through the National Procedure – UK case study

Data from the UK competent authority show the final outcome of each application – whether it was issued, withdrawn by the applicant over the course of the process, or not issued (i.e. rejected). Figure A6.41 shows the results of the analysis.

Figure A6.41 Of the 529 applications for a new MA that were received by the UK competent authority between 2000 and 2009, all but 3 were issued with a MA, with this pattern being largely repeated across the other application types. Type II variation applications were the most likely to be rejected, although the proportion of the total number of applications rejected was small (5 per cent)

The outcome of applications, by type of application (2000-2009)

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>New MA</th>
<th>MA renewal</th>
<th>Type IB Variation</th>
<th>Type II Variation</th>
</tr>
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<td>Withdrawn</td>
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<td>152</td>
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<tr>
<td>Not Issued</td>
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Source: GHK analysis of MA databases
Annex 7  Detailed Standard Cost Model Results

Table A7.5  Details of the SCM for the legislative framework for veterinary medicinal products

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<tr>
<th>Activity</th>
<th>MA procedure/details</th>
<th>Staff cost per hour</th>
<th>Staff time hrs</th>
<th>No. actions per entity p.a.</th>
<th>Staff costs per action</th>
<th>Staff costs per entity p.a.</th>
<th>Equip costs per action</th>
<th>Equip costs per entity p.a.</th>
<th>O/S costs per action</th>
<th>O/S costs per entity p.a.</th>
<th>Total no. of entities</th>
<th>Total no. of actions p.a.</th>
<th>Total cost p.a.</th>
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</table>
### Table 1: Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

<table>
<thead>
<tr>
<th>Activity</th>
<th>MA procedure/details</th>
<th>Staff cost per hour</th>
<th>Staff time hrs</th>
<th>No. actions per entity p.a.</th>
<th>Staff costs per action</th>
<th>Staff costs per entity p.a.</th>
<th>Equip costs per action</th>
<th>Equip costs per entity p.a.</th>
<th>O/S costs per action</th>
<th>O/S costs per entity p.a.</th>
<th>Total no. of entities</th>
<th>Total no. of actions p.a.</th>
<th>Total cost p.a.</th>
</tr>
</thead>
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<td><strong>Applying for a MA renewal</strong></td>
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<td>184,350,250</td>
<td>184,350,250</td>
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<td><strong>Sub-total</strong></td>
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<td></td>
<td></td>
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<td>537,852,751</td>
</tr>
</tbody>
</table>

*Notes: All costs are in EUR; n/a means not available; Equip means equipment costs; O/S means outsourced costs*

*Source: GHK analysis*
Annex 8  The Veterinary Medicinal Products Industry

The purpose of this Annex is to provide a short profile of the veterinary medicinal products industry in Europe, based on publicly available information on the sector, and drawing on an analysis of authorised products and product applications, which includes information on the identity of the MA holders.

This review has been limited by the lack of availability of publicly available data. EU-wide datasets (such as Eurostat) do not distinguish between animal and human pharmaceuticals, meaning that it has been difficult to obtain accurate estimates of the size and nature of the sector, and the trade in its products.

IFAH-Europe, an organisation representing companies in the sector, has published estimates of the relative size of the two industries. It has estimated that, globally in 2007, the animal pharmaceuticals industry was 2.4 per cent of the size of the human pharmaceuticals industry.

Other reports produced by the industry are useful, though do not cover the entire EU/EEA, are not published regularly, and do not allow for a level of disaggregation that is needed. It has also been impossible to independently verify the results presented.

A8.1  Sales and Employment

A8.1.1  Sales

Data on annual sales within the animal health industry are available from IFAH and its European federation, IFAH-Europe. Figure A8.42 shows the total value of the global and European animal health markets (no information is available on the identity of countries included within either the global or European markets). Figure A8.43 provides data on market sizes in four countries for which data were available: France, Spain, Germany and the UK. Finally, Figure A8.44 shows market size data for five key therapeutic categories of veterinary medicinal products (it has not been possible to provide data based on the ATCvet categories used previously).

The global animal health industry had sales estimated at over €13.4 billion in 2009, with sales in Europe estimated at €4.6 billion (at 2005 prices). Between 2005 and 2008 the size of the European market increased by 23 per cent in real terms (compared to an increase of 18 per cent globally), before dropping back to its 2007 level in 2009. Of the four countries for which market data have been identified, France had the largest animal health market, worth €1.08 billion in 2009 (at 2005 prices).

49 IFAH-Europe (2008) Facts and Figures about the European Animal Health Industry. It was reported that the global market value of the human pharmaceuticals industry was $650 billion, as opposed to $16 billion for the animal pharmaceuticals industry (date unknown).
Figure A8.42 Europe accounts for about a third of the global animal health market


Source: IFAH (Global market); IFAH-Europe (European market)

Figure A8.43 Four national markets account for around two thirds of the European market

*Annual animal health industry sales, in EUR billions, at 2005 prices (2007-2009), for selected national markets*

Source: Animal Pharm

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Industry data suggest that, measured by annual sales, parasiticides and vaccines were the two largest markets (jointly accounting for 54 per cent of the total). Of the five therapeutic categories, sales of vaccines grew the most between 2006 and 2009 (an increase of 37 per cent in real terms), whilst sales of antimicrobials grew the least (an increase of 6 per cent in real terms).

Figure A8.44 Vaccines and parasiticides are the two largest market categories

A8.1.2 Employment

IFAH-Europe has estimated direct employment in the sector – in production, marketing, sales, administration and R&D – at 15,000 jobs. The same source estimates indirect employment sustained in the sector’s supply chain at 19,000 jobs, with a further 16,000 sustained through multiplier effects in the wider economy.

Eurostat data indicates that, in 2007, a total of 606,500 people were employed in the pharmaceutical manufacturing industry in Europe. If, as IFAH suggest, the animal pharmaceutical industry has sales worth 2.4 per cent of the human pharmaceutical industry (see introduction to chapter), this would suggest that around 14,600 people are directly employed by the veterinary medicinal products manufacturing industry in Europe – a figure comparable to the 15,000 estimate above.

As part of the business survey, companies were asked to report their current employment in Europe. The 17 businesses that responded to the survey employed a total of 9,975 people, an average of 587 people per business. Survey respondents were considerably larger than

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54 Animal Pharm News http://www.animalpharmnews.com/
55 17 EU/ EEA countries: AT, BE, CH, CZ, DE, DK, ES, FR, EL, HU, IE, IT, NL, PL, PT, SK, UK.
59 The EU/EEA-30 minus: IS, CY, MT, LI, SI, EE, and LU
the sector average since they included 9 of the 10 largest businesses in the sector, but this again suggests that the 15,000 employees estimate is reasonably accurate.

A8.2 The Structure of the Sector

A8.2.1 The Total Number of Businesses in the Sector

The veterinary medicinal products sector is made of businesses that fulfil a number of roles, including:

- R&D and the development of new products;
- The manufacture of veterinary medicinal products (original or generic products);
- Importing products; and
- Wholesale of products.

In many cases businesses fulfill more than one of these roles, such as companies that both develop and manufacture products (potentially including generic versions of existing products). In other cases, business specialise, for instance by manufacturing products on behalf of others, or importing licensed products that have been manufactured elsewhere.

Eurostat includes data on the number of businesses that manufacture pharmaceuticals, but does not distinguish between animal and human pharmaceuticals manufacture. In 2007, data suggest that there were a total of 4,493 pharmaceutical manufacturers in Europe. If, as noted earlier, the animal pharmaceutical industry is 2.4 per cent of the size of the human pharmaceutical industry and the structure was exactly comparable, this might suggest that there were around 108 manufacturers in Europe, but this is a crude and unsatisfactory measure of the sector population.

An alternative measure of the size of the sector would be the number of businesses that hold MAs, information that is available (at least in part) though public databases. The identity of the MA holder was provided by 18 of the 19 competent authorities that provided data on authorised products, though this list excludes data on MA holders in 12 countries, including large countries (and markets) such as Spain and Italy.

A total of 463 unique MA holders were identified in the 18 countries that provided the necessary information. Figure A8.45 shows how many MA holders were present in each of the countries that provided data. To estimate the total number of MA holders in the EU and EEA, it has conservatively been assumed that the country level analysis captured all of the MA holders that serve more than one national market, and thus that the only omission is businesses that serve only one market. Among the 18 countries studied, there was an average of 14 MA holders per country which only served that one national market. Grossing this figure up to the remaining 12 countries suggests that there could be a further 131 MA holders active in those countries for which data were not available for this study – i.e. 594 MA holders in total.

There are, however, complicating factors:

- First, this estimate is not fully adjusted for merger and acquisition activity in the sector. The MA databases record the name of the company making the application, but if that company is subsequently taken-over by another, the record in the database is not generally updated.
- Second, and perhaps more significantly in the present context, the population of Marketing Authorisation holders includes a range of different types of businesses -

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60 Defined as the EU/EEA-30 minus IS, MT, CY and LI
61 For the purposes of this section of the report, all MA holders are described as ‘companies’ even though in practice a small percentage of them are not private sector entities (e.g. universities)
62 Belgium, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Lithuania, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia and the UK
manufacturers, licence holders, importers etc. Interrogation of the raw data suggests that there organisations – such as universities and consortia of veterinarians – which hold MAs but which are unlikely to manufacture products.

Figure A8.45 There were, on average, 89 unique MA holders on each national market. The number of MA holders was closely linked to the size of the country (measured by the human population). Smaller countries (such as Malta and Cyprus) had the smallest number of MA holders

The number of unique MA holders on national markets, as at May 2010

Source: GHK analysis of MA databases
Annex 9 Case studies of risks to human and animal health

This Annex presents two case studies which demonstrate the linkages between availability of veterinary pharmaceutical products to animal and human health risks and to the legislation framework governing those products.

Veterinary medicines enable the treatment and control of animal diseases and the maintenance of good animal health. When veterinary medicines are scarce there is the potential for animal health risks to increase. Some diseases can pass from animals to humans, creating the potential for a link between risks to animal health and human health. A market that is well serviced with veterinary medicines, and which encourages innovation to address new and emerging health risks, ought therefore to offer benefits to both animals and humans.

This section explores this issue through case studies focusing on:

- Bluetongue, in order to investigate the impact of the current legislative framework for veterinary medicinal products on animal health; and,
- Avian influenza, in order to explore the impact on human health.

The discussion also discusses aspects of the current legislation framework which have been identified by the animal health industry as posing barriers to the prompt and cost-effective delivery of products which can tackle such conditions.

A9.1 Bluetongue

A9.1.1 Introduction

Bluetongue is an insect-borne viral disease that affects ruminants and camelsids, including sheep, cattle, goats and deer.\(^{63}\) The bluetongue virus (BTV)\(^{64}\) is transmitted by biting midges (Culicoides) and is one of the most widespread animal pathogens in the world. Clinical signs vary across ruminants and ruminant breeds, both in severity and type, with sheep being the most severely affected. Bluetongue outbreaks over the last decade have primarily affected sheep and to a much lesser extent, goats. However, a major outbreak in 2007 affected a wider range of species, including cattle, goats and camelsids.\(^{65}\)

The bluetongue disease is characterised by inflammation and haemorrhages to the mucous linings of the mouth, nose and the coronary band of the foot, but also includes fever, lameness and muscle degeneration.\(^ {66}\) Swelling of the face is commonly seen in sheep. The mortality rate is high in susceptible sheep flocks and may reach 80 per cent, though the mortality rate depends on the virus serotype and immunity status of the affected population.\(^ {67}\) Historically, cattle exhibit clinical disease signs in fewer than 5 per cent of cases and bluetongue rarely results in mortality.\(^ {68}\) However, signs have been seen more commonly in cattle in the recent outbreak in Northern Europe.

A9.1.2 Origins and Geographic Distribution

Bluetongue originated in South Africa and has been formally recognised since 1905 as ‘bluetongue’, though it was first described in the 19th century.\(^ {69}\) The disease is now

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\(^{63}\) Bluetongue does not affect pigs, horses or humans

\(^{64}\) BTV is a member of the Orbivirus genus in the family Reoviridae


\(^{68}\) ibid

widespread, and has been found on every continent except Antarctica in a latitudinal band stretching from 40°S to 53°N. Bluetongue is considered to be an established enzootic disease in Europe and it has become more prevalent and extended its range over time. Climate change and globalisation are regularly cited as contributing factors to this phenomenon, allowing the vector to spread beyond its normal range in the first instance, and facilitating the importation of infected animals in the second. The recent outbreak of disease in Northern Europe was completely unexpected and affected a naïve population of animals, making its effects all the more devastating.

A9.1.3 Monitoring and Disease Control

There are 24 distinct BTV serotypes, six of which have been present across Southern Europe since it was introduced to Greece in 1998. Serotype 8 has spread across Northwestern Europe during 2007 and further serotypes have made incursions into Northern Europe. While bluetongue is one of the best understood diseases, there are no known cures. Surveillance and protection zones are established during bluetongue outbreaks. These involve animal movement restrictions and may also include slaughter and vaccination where appropriate. Livestock movements within a protection zone are permitted, but exports must meet International Trade requirements set out in the EU bluetongue regulations.

Animal keepers must obtain licenses for ruminant transit into, out of and through bluetongue zones, as well as general licenses being required in each country for animal vaccination. Governments provide export health certifications to assist businesses and individuals export animals and animal products. Member States implement vaccination schemes according to their own national policies, the geographic distribution of the disease and vaccine availability.

Effective monitoring and surveillance can prevent the disease from spreading, and a range of vaccines for different serotypes are commercially available as a preventative measure. Often vaccines protect against a particular serotype, though multivalent vaccines are available in some cases. This factor, coupled with the existence of a large number of serotypes, complicates vaccination strategies. Additionally, there are a number of drawbacks to the currently available vaccines, which are explained in greater detail below.

A9.1.4 Disease Impacts

Bluetongue is classified as a disease by the World Organisation for Animal Health because it can spread rapidly and has a large impact on animal health. For example, a report from

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70 Enzootic refers to a disease that is constantly present in a particular geographic area.
71 Historically, BT global distribution was between 35° S and 40-50°N but the recent BTV-8 epidemic in northern Europe extended its range beyond its known northern limits (Savini et al 2008).
74 Serotype refers to a closely related set of microorganisms distinguished by characteristic antigens (i.e. substances that trigger an immune response).
75 Serotypes 2, 4, 9 and 16 are commonly found in Southern Europe; serotype 1 has been present as well. In 2006, serotype 8 was found in Belgium, France, Germany, Luxembourg and the Netherlands. BTV 1 was identified in France in 2007 and has spread quite widely. In 2008 BTV 6 was identified in the Netherlands and Germany, and BTV 6 and 11 in Belgium. These latter two outbreaks were very isolated and it has been suggested they could have arisen from reversion to virulence of illegally-used modified live vaccines. A bluetongue-related virus, Toggenburg orbivirus (BTV 25), has also been found in Switzerland.
76 Earlier BT outbreaks have been recorded in Cyprus in 1943, and possibly as early as 1924. A BTV-10 outbreak occurred in Spain and Portugal between 1956 and 1960. Bluetongue epidemics have been reported in Greece from 1979 to 1999 (Calistri et al 2004). But the first major outbreak to establish bluetongue across Mediterranean Europe occurred in 1998.
2006 estimated that bluetongue outbreaks in Europe since 1998 had resulted in the death of more than 1.5 million sheep. Another report estimated that outbreaks of BTV-2 and BTV-9 in Italy from 2000-2002 resulted in animal losses of more than half a million sheep and goats, most of which were slaughtered to prevent the disease from spreading.

Bluetongue also results in considerable negative economic impact due to mortality and reduced production in affected livestock, and because of a nearly total ban on ruminant trade between BTV-infected and non-infected areas. Direct economic losses from bluetongue occur through animal death and reductions in productivity due to clinical impacts on health. Lack of effective treatment and extensive nursing requirements result in large numbers of affected animals being humanely destroyed. Lack of productivity and infertility can cripple the remaining animals in a flock or herd. Indirect economic losses can be much greater, and stem from the restrictions in trade that occur during outbreaks (both animal movement and cattle semen export restrictions) and costs associated with implementing control measures.

Economic losses associated with the BTV-8 outbreak in 2007, for example, were estimated at US$1.4 billion in France and US$85 million in the Netherlands.

A9.2 Avian Influenza

A9.2.1 Introduction

Avian influenza is a highly contagious viral disease that affects many bird species and some mammals. It is also known to infect humans in rare cases, but there is little evidence that it can spread from person to person. Avian influenza does have the potential to recombine with human influenza, however, to create a global pandemic that spreads easily between people.

Avian influenza is not an airborne disease, but rather spreads through contact with infected animals’ secretions, especially faeces. Wild waterfowl are thought to carry the disease in virtually all of its forms and to transmit the disease to domesticated poultry and other birds. Low pathogenic viruses (LPAI) may cause no obvious symptoms in birds, but highly pathogenic forms (HPAI) can cause respiratory problems, swollen heads, appetite loss, diarrhoea and reduced egg production. Highly pathogenic forms spread rapidly (within 48 hours) and can result in avian mortality rates approaching 100 per cent. In humans, avian influenza can cause severe respiratory disease and has been fatal in approximately half of laboratory-confirmed cases to date.

A9.2.2 Origins and Geographic Distribution

The origins of avian influenza are unknown, but it was first documented as a severe chicken disease in Italy in 1878. Avian influenza is present worldwide and was documented in the United States from 1924-1925, 1929 and 1983-1984. A serious outbreak of HPAI in the

81 Direct animal deaths were estimated at approximately 120,000; the number of slaughtered animals was more than 400,000.
Netherlands in 2003 spread to Belgium and Germany. Another major outbreak occurred in South East Asia in 2004, and again in 2006 and began to spread through Europe and Africa. Early detection and effective culling of contaminated animals is thought to have halted the spread of avian influenza during this latest outbreak.

A9.2.3 Monitoring and Disease Control

There are three different influenza virus species: influenza A is responsible for avian influenza and consists of several distinct subtypes; B viruses do not have subtype variations and infect only humans while C viruses infect humans and pigs but are not associated with epidemic or pandemic human disease. Influenza A is primarily found in waterfowl though it causes little or no disease in these birds. There are 15 H subtypes and 9 N subtypes of the influenza A virus, which can be found in virtually all combinations in waterfowl (e.g. H1N1). The majority of outbreaks recently seen in Asia and Europe have been due to the H5N1 subtype.

Protection and surveillance zones are established where avian influenza cases are confirmed, which may include isolating or housing poultry or other captive birds, restricting animal movements, slaughtering infected birds and eggs, and other measures. Restriction zones may also be declared, which restrict poultry and egg movements to licensed animals.

Early detection, isolating domestic poultry from wild birds and culling contaminated animals has so far been effective at preventing the spread of avian influenza in Europe. If wild bird infections grow in duration or severity, or if transmission risk to domestic poultry increases significantly, vaccination programs will be required. This means that vaccine contingency plans must be in place before an outbreak occurs.

A9.2.4 Disease impacts

Avian influenza is a serious potential threat to global human health because avian influenza is known to recombine with human influenza virus, the potential for a new virus to emerge that spreads quickly and easily between people is a possibility.

The avian influenza outbreak in Europe in 2003 necessitated the slaughter of more than 28 million poultry. Recent major outbreaks across Asia from 2004 to 2006 resulted in the destruction of millions of birds. The most recent outbreaks reached Turkey, including several confirmed human cases. Small numbers of wild and domestic bird cases have been reported across Europe from 2006 to the present. By 2008, more than 300 human avian influenza cases and approximately 90 human deaths had been recorded by the World Health Organisation. Most cases are thought to have resulted from direct contact with infected birds. A limited number of cases of human to human transmission have been reported.

The number of human infections has thus far remained low, but the emergence of a new virus strain that spreads between humans, and for which the global population has limited immunity may infect up to 35 per cent of the world’s population according to World Health Organisation estimates. Two million deaths are a conservative estimate of the human

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89 Ibid
91 Defra (2010) Op cit
health impact of a major pandemic\textsuperscript{96}. Larger mortality estimates of 360 million and even as high as 1 billion have been reported\textsuperscript{97}.

### A9.3 Bluetongue and Avian Influenza Vaccines

There is no known cure or treatment for bluetongue or avian influenza. Vaccination is the only effective protective measure, though a range of other options have been implemented in different countries over time including slaughter of infected animals, the use of ectoparasiticides\textsuperscript{98} and housing livestock during outbreaks.

An ‘ideal’ vaccine is considered to have the following characteristics: low production costs, require a single dose for long-term protection, allow a vaccinated animal to be distinguished from an infected animal (DIVA), does not revert to virulence or recombine with circulating virus, provides protective immunity against multiple serotypes and has the lowest number of negative side-effects (e.g. clinical symptoms, abortion, reversion to virulence, etc.). All available vaccine options have potential advantages and disadvantages (see Table A9.6).

#### A9.3.1 Bluetongue

BTV productively infects only ruminants; therefore, no small animal models exist to perform vaccine trials, resulting in high associated costs for bluetongue vaccine development\textsuperscript{99}. Consequently, only modified live virus (MLV) and some inactivated vaccines are currently available under the European Commission approved national disease control programmes. MLVs are the mostly widely available commercial option. Inactivated whole virus preparations are also commercially available.

MLVs are cheap to produce at scale and only require a single dose. MLV vaccines are commercially available for 15 different serotypes, providing wide coverage, and are generally effective in preventing clinical bluetongue disease where they are used. MLVs, however, can result in mild clinical signs following injection, abortions and depressed milk production\textsuperscript{100}. Disease can spread through reversion to virulence and may combine with wild virus to create new strains. Animals injected with an MLV vaccine are indistinguishable from an infected animal, inhibiting trade during outbreaks.

Inactivated whole virus vaccinations are very safe when properly produced and highly efficacious\textsuperscript{101}. Methods for differentiating infected from vaccinated animals are not yet available, but the potential exists. Disadvantages include high production costs and the need for booster immunisations. They have been the vaccine of choice for areas of epizootic disease, due to the risks involved in using MLVs. Inactivated BTV 8 vaccine has been widely used in Northern Europe.

Gene-based vaccines have numerous potential benefits including rapid onset of immunity, lack of transmissibility and the potential to protect against more than one serotype\textsuperscript{102}. They are considered to be naturally safe and do not require inactivation to be effective. Recombinant vaccines are still at a developmental stage; their field efficacy is still under evaluation.


\textsuperscript{97} Ibid

\textsuperscript{98} Ectoparasiticides are drugs used to treat or prevent external parasitic infestations.


\textsuperscript{102} Ibid
### Table A9.6  There are a number of vaccine options for bluetongue and avian influenza

<table>
<thead>
<tr>
<th>Vaccine options</th>
<th>Bluetongue</th>
<th>Avian influenza</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Vaccine options</strong></td>
<td><strong>Advantages</strong></td>
<td><strong>Disadvantages</strong></td>
</tr>
<tr>
<td>Live attenuated vaccines: modified live virus (MLV)</td>
<td>Temporarily controls BTV in certain areas and reduces clinical impact of disease; inexpensive to produce; single dose required</td>
<td>Teratological effects(^{103}); depressed milk production; transmission to non-vaccinated animals, implicated in spread of disease; non-DIVA</td>
</tr>
<tr>
<td>Inactivated virus vaccines</td>
<td>Produces good immunogenicity; safe; more effective than MLVs; DIVA potential; less likely to cause spread of disease</td>
<td>Must be completely inactivated to avoid similar MLV problems; requires two doses and growth of large amounts of antigen to produce vaccine (high costs); lengthy production time (6-8 months)</td>
</tr>
<tr>
<td>Gene-based vaccines (virus and bacterial vector-based)</td>
<td>Low risk of reversion to virulence; no reassortment; potentially safe; DIVA potential; potential for multiple-serotype protection</td>
<td>Efficacy currently no greater than for inactivated virus vaccines and requires several doses for long-term protection; field efficacy unknown</td>
</tr>
</tbody>
</table>

\(^{103}\) Teratological effects are developmental defects (e.g. congenital malformations) and can lead to foetal death
A9.3.2 Avian Influenza

Inactivated virus vaccines for avian influenza have been available for more than 30 years for a number of virus serotypes to help prevent and control the spread of the disease and are recommended for use in conjunction with other effective control measures\(^\text{104}\). Live recombinant vaccines are also becoming available\(^\text{105}\). Both vaccine types allow for differentiation between vaccinated and infected birds (DIVA), which is important for controlling disease and preventing unnecessary animal slaughter. While current vaccines do not prevent avian influenza infections, they do significantly reduce the clinical severity of the disease and transmission between birds.

There are a number of disadvantages to inactivated vaccines, however, including the need to inject each individual bird twice, which results in high vaccination costs. Immunity takes 2-5 weeks, which leaves a window for infection. Vaccination is also problematic for laying hens because handling results in depressed egg production and potentially peritonitis\(^\text{106}\), which can be fatal\(^\text{107}\). Finally, each vaccine protects against only one virus strain at a time; the introduction of a new avian influenza strain would necessitate a new round of vaccination, and thus the development of multiple vaccines.

Vaccine use is controlled by EU law, given the risk to trade of their uncontrolled use. In December 2005 vaccination was approved for use in domestic poultry and zoo species, subject to EC approval of the individual countries’ vaccination plans. The limitations of the currently available vaccines are decreasing their use. For example, routine vaccination of domestic poultry is not currently recommended in the UK. One reason is due to the perceived risk of being unable to rapidly identify and deal with new virus incursions into vaccinated flocks. However, vaccination would be recommended in high risk situations or as an emergency disease control measure, making the rapid availability of up to date, efficacious vaccines a priority.

Moreover, vaccine development is complicated by the constant evolution of influenza viruses and their rapid spread resulting in a very tight timeframe for developing, manufacturing and delivering a new vaccine during outbreaks\(^\text{108}\).

A9.4 Regulatory Issues

During a disease outbreak, the fastest route to a licensed vaccine is to obtain national authorisation under exceptional circumstances, for which limited data are considered sufficient. National authorisation under exceptional circumstances can take as little as one week for approval.

Currently, however, EU legislation does not provide for exceptional Marketing Authorisations that extend beyond a single state when a national Marketing Authorisation is sought. Each country has different requirements for approval, which increases the administrative burden on companies seeking authorisation. Furthermore, approval can be revoked at any time by a country under exceptional circumstances, so that companies undergoing product development, which typically takes between 6-8 months, may find that their temporary license is revoked before the drug reaches the market, resulting in significant financial losses for the company.


\(^{106}\) Peritonitis is an infection of the membrane that lines the abdominal wall and covers the abdominal organs.

\(^{107}\) British Veterinary Association (BVA) (2007) Op cit

Conversely, while the centralised EU authorisation procedure could provide pan-European coverage for a new vaccine. However, in consultation representatives from the animal health industry suggested that the documentation procedures associated with these channels extend the time taken for authorisation and so impact negatively on the availability of new vaccines. It has been reported that licensing under exceptional circumstances can take as long as full market approval. At EU-level the exceptional circumstances approvals process can take from 5 months to more than a year. This is particularly problematic in emergency situations; diseases such as bluetongue and avian influenza can spread in as little as a couple of months.

From an industry perspective, licenses for use under exceptional circumstances are perceived to have a number of drawbacks which disincentivise companies from seeking them.

First, manufacturers are required to take a conditionally licensed product to full market approval, regardless of whether the disease threat remains and vaccines are required. Companies then must either withdraw the product and bear the losses already incurred in its development, or continue with the process and pay the associated testing, reporting and maintenance costs without any investment returns. It has been suggested that allowing companies to ‘freeze’ the conditional licensing transition to full Marketing Authorisation until such time as vaccines are again required would help alleviate this burden and encourage product development through exceptional circumstance licenses.

Second, the data requirements for EU-wide approval under exceptional circumstances are more stringent and time-consuming than obtaining emergency use authorisation in an individual Member State, even where the same product has been approved in one or even several Member States and is under application for an EU license. Interviews with industry representatives suggest that the reason for this is that satisfying multiple Member States is far more difficult than satisfying only one.

A third issue is the restriction on what types of product can be authorised under the exceptional circumstances clause. Currently only inactivated vaccines may be authorised, limiting the range of options available to combat emerging diseases. Live vaccines present too many safety risks for emergency authorisation given the relatively reduced data requirements of this license, but other potential options – such as recombinant vaccines – could be considered but are essentially ineligible for use in emergency situations. The limited prospect of approval creates a disincentive for companies to develop new types of vaccine product.

Fourth, multi-strain dossiers are not permitted under exceptional circumstances. Multi-strain dossiers allow companies to seek Marketing Authorisation for more than one virus strain at a time. For diseases such as bluetongue and avian influenza, which emerge in different forms over time, multi-strain dossiers can significantly alleviate the data reporting burdens and administrative costs associated with obtaining a license. But each of these diseases also tends to appear suddenly, requiring a speedy authorisation process, with significant time periods in between with no disease activity in Member States. The multi-strain dossier, which only applies to three diseases (including foot and mouth disease), is therefore disallowed in those situations where they would be most useful (i.e. when Member States desire vaccines through the exceptional circumstances clause).

A recent industry assessment observes that vaccine development is currently hindered by onerous regulatory requirements whereby a new set of regulatory documents must be produced detailing the quality, safety and efficacy of each new vaccine developed to correspond to changes in circulating virus strains.

Finally, the EU veterinary pharmaceuticals legislation currently does not allow provisional licenses. In essence, this prevents companies from developing products for diseases that have not yet reached Europe. But the timeframe for developing a new product is a minimum

\[109\] Submission by International Federation for Animal Health (IFAH) to the study team, unpublished. 2010.
\[110\] Ibid
of 6-8 months for bluetongue and avian influenza. Currently, companies must wait until a disease has emerged to initiate the application procedure, which takes at least half a year (and up to 1.5 years) under ideal circumstances. By the time approval has been granted, and the product developed, the disease may have run its course, and vaccines no longer required.

The industry argues that there would be benefits in an EU-wide license available under exceptional circumstances that:

▪ Is less time-consuming from application to approval;
▪ Has fewer data requirements given the emergency nature of the disease outbreak;
▪ Can be used for more than ‘classic’ vaccines (i.e. gene-based in addition to inactivated vaccines) to encourage innovation;
▪ Provides a multi-strain dossier option for diseases that tend to break out under emergency conditions where there are many strains and difficulty predicting which strain will emerge at a given time; and
▪ Allows companies to submit provisional licensing applications for diseases that may (re)emerge in Europe, but have not yet done so.
Annex 10  Case study of the usage of the cascade

A10.1  Antibiotic footbath use in the UK

A10.1.1  Economics of lameness

Lameness in cattle and sheep is one of the biggest causes of economic loss and decreased animal welfare in UK farming. Prevalence of lameness varies greatly between farms, but several studies have found around 20 per cent to 40 per cent of dairy cattle lame at any one time\textsuperscript{111,112}. Annual incidence of lameness has been estimated as 55 cases per 100 cattle (range 2-200 cases)\textsuperscript{113}. DEFRA figures for June 2009 show the UK dairy herd to stand at 1.86 million. Average cost of a case of lameness in a dairy cow is estimated to be £180 - 240\textsuperscript{114}, giving an annual cost to the industry of around £200 million. This is more than double the annual cost reported in 1990\textsuperscript{115}.

There are also 14 million sheep in the UK, and the prevalence of lameness is known to be 6-11 per cent\textsuperscript{116,117}; however there is again a great variation between farms. The cost of sheep lameness due to foot rot alone (the most common cause of sheep lameness) is estimated at £24 million annually\textsuperscript{118}.

A10.1.2  Background: Digital Dermatitis and Contagious Ovine Digital Dermatitis

Digital dermatitis (DD) is an infectious skin condition of cattle, causing pain and inflammation of the skin of the heel bulbs and between the digits. The pathogenesis and aetiology of the disease is not fully understood, but it is believed that Spirochete bacteria (genus Treponema) are the likely cause. Lesions can become longstanding and act as a reservoir of infection for the rest of the herds. Spread is associated with slurry, passing the organism between the feet of cattle. DD has a marked seasonal variation in many herds, but is thought to be responsible for between 15 per cent and 40 per cent of total lameness cases\textsuperscript{119,120}. Over 70 per cent of UK dairy herds are affected\textsuperscript{121}, as well as some beef units. Estimates of the cost of DD suggest direct costs of £90 and total costs of £193 per case\textsuperscript{122}.

CODD is virulent, infectious form of lameness in sheep, first identified in 1997, although it had been present in the UK since the late 1980s. It is currently believed to have a similar aetiology to DD in cattle\textsuperscript{123}. It causes inflammation and ulceration at the heels and coronary band of the hoof and can lead to separation and shedding of the hoof capsule. Partly due to lack of awareness and incorrect diagnosis by farmers, it has spread over recent years and is


\textsuperscript{117} Kaler J and Green L. Survey of farmer-observed lameness on 800 sheep farms –University of Warwick 2007


now thought to account for 25 per cent of lame sheep\textsuperscript{124}, although many farms are not aware of the disease.

A10.1.3 Treatment and control options

Treatment and prevention of DD and CODD is difficult. Management improvements are important in reducing lameness but, as these are infectious problems, antibacterial therapy is usually required. Individual animals often respond well to topical treatments applied to the foot, such as repeated application of licensed antibiotic sprays, or bandaging of antibacterial compounds onto the foot\textsuperscript{125}. However, rapid recycling of disease through a flock or herd makes treating animals individually time consuming, ineffective and uneconomic. Injectable antibiotic treatments suffer from the same problems, as well worries about antibiotic residues in cow’s milk with many products. There is one injectable product licensed against DD in cattle: Cobactan 2.5\% (cefquinome, Intervet Schering-Plough Animal Health). Certain injectables are instead licensed in a general sense, where infections are caused by organisms sensitive to them e.g. Tylan 200 (tylosin, Elanco Animal Health) is generally active against Spirochetes and is licensed in cattle. Limited work has been done regarding the efficacy of systemic treatments in DD. One study found a five day course of cefquinome to be as effective as erythromycin foot bathing twice\textsuperscript{126}. Anecdotal evidence suggests Micotil (tilmicosin, Elanco Animal Health) is one of the only effective systemic treatments for CODD in sheep, but ‘vet only’ administration limits its usefulness on commercial sheep farms. However, it is widely believed that injectable antibiotics are not very effective in treating DD or CODD.

Foot bathing is thought to be an effective whole herd or flock control measure for DD\textsuperscript{127,128} and CODD\textsuperscript{129,130}. Various products are used in footbaths. The most common non-antibiotic options are formalin, copper/zinc sulphate, peracetic acid, sodium hypochlorite and various proprietary combinations also containing surfactants and peroxides. These have a place in the control of DD/CODD, as well as other causes of lameness, but are often not effective enough used alone. In addition, foot bathing in formalin or high levels of peroxides could be extremely painful with the open lesions of DD or CODD. Hence unlicensed antibiotic foot bathing has become widespread (usually using soluble lincomycin, spectinomycin, erythromycin or tylosin), with the belief that it is the most effective and ‘cow friendly’ treatment.

Dawson\textsuperscript{131} reported that between 70 per cent and 100 per cent of dairy farms with DD used antibiotic footbaths, although current anecdotal evidence suggests this may now not be as high. Several regimens have recently been advocated for antibiotic foot bathing (University of Bristol): use every 4-6 weeks during the winter (housing period), targeted use (e.g. at drying off or addition of new animals to the milking herd), or before starting to use another type of footbath (e.g. formalin).

In the absence of confirmed recent data, an estimate of the frequency of antibiotic foot bathing has been made, giving highest and lowest estimates for comparison. Foot bathing of some type is carried out at least weekly on many dairy farms, but antibiotics are only likely to

\textsuperscript{124} Kaler J and Green L. Farmers’ practices and factors associated with the prevalence of all lameness and lameness attributed to interdigital dermatitis and footrot in sheep flocks in England in 2004. Preventive Veterinary Medicine (2009)
\textsuperscript{125} Nishikawa and Taguchi. Healing of digital dermatitis after a single treatment with topical oxytetracycline in 89 dairy cattle. Veterinary Record (2008) 163, 574-576
\textsuperscript{127} Laven R (2001) \textit{Op cit.}
\textsuperscript{128} DEFRA (2008) \textit{Op cit.}
\textsuperscript{130} Scott (2010) \textit{Op cit.}
\textsuperscript{131} Dawson, J C. Digital dermatitis - survey and debate. Proceedings of the XXth World Buiatrics Congress, Sydney.1998 pp 91-93
be used when a farm is suffering a major outbreak of disease, or when new animals are added to the herd. Used at the worst times of year and/or alternated with other products, an estimate of between 5-10 antibiotic footbaths per year could be made. There will be a great variation in this between farms, areas and with the time of year. It has been suggested that antibiotic footbath may have to be used weekly to get infection under control. If 5-10 antibiotic footbaths were used annually by between 10 per cent and 50 per cent of UK dairies, this would equate to between 1 million and 10 million individual cow treatments per year.

A10.1.4 Concerns regarding use of the unlicensed product

There are several issues surrounding these treatments: potential for antibiotic residues in milk and the application of standard withdrawal periods; use of an unlicensed product within the rules of the cascade; development of antibiotic resistance; and disposal of large amounts of antibiotic solution.

Antibiotic residues are a major concern to the dairy industry, with small amounts of contamination potentially condemning millions of litres of milk. Few published studies have investigated the use of antibiotic footbaths in this respect. One such study\(^ {132}\) showed minimal systemic absorption of erythromycin following foot bathing. However, the potential for contamination will depend very much on the individual system used for foot bathing and how quickly cattle are milked afterwards. Even if systemic absorption of the product is minimal, contamination of the cattle’ udder is still possible. Any ‘cascade’ use of a product requires a minimum standard withdrawal to be applied (minimum 7 days for milk, 28 days for meat). The full standard milk withdrawal is likely to be widely flouted with regard to the use of antibiotic footbaths.

Antibiotic resistance is becoming an increasingly important concern in veterinary species, especially where routine use is an issue. Controlled use, at the correct dosages, is known to decrease the build up of resistance. With unlicensed products, there is only anecdotal evidence of the correct concentrations to use, and the correct method of usage (e.g. contact times and topping up of the footbath).

Disposal of footbath solutions (antibiotic or non-antibiotic) is a risk, when no specific guidelines are provided. The most common method of disposal is mixing with the slurry system, so any product is extremely diluted. However there appears to be little knowledge of the effects of this, which would be addressed with a licensed product.

The prescribing cascade only permits the use of an unlicensed product when there are no licensed alternatives. In the case of DD, the licensed products are useful for control of small numbers of cases, but not a herd problem. Hence it is unclear for prescribing vets where the line should be drawn when recommending the unlicensed antibiotic footbath. In the case of DD or CODD, not being able to prescribe an effective herd or flock treatment would have serious effects on animal welfare. However, after more than 10 years of research into DD and CODD, few certain guidelines are available on antibiotic foot bathing and no licensed products have become available. It is clear from the above calculations that a significant potential market for a licensed product exists, so it must be assumed that there is a commercial reason for the lack of this.

The benefits of a licensed antibiotic-based product would be:

- Confirmed efficacy and safety
- Guidance on dose and method of use
- Guidance on disposal
- Withdrawal periods established


\(^ {133}\) Hartog B J, Tap S H M, Pouw H J, Poole D A, Laven R A. Systemic bioavailability of erythromycin in cattle when applied by footbath. Veterinary Record (2001) 148, 782-783
Knowledge and monitoring of resistance patterns

It appears unlikely that any of the above factors would be insurmountable in gaining a Marketing Authorisation. It could therefore be assumed that the current use of products is acting as a disincentive to develop new products. While allowing effective treatment and improvement of animal welfare, the cascade use of unlicensed antibiotic foot baths does suffer from several concerns already mentioned.

The marketing of other, non-medicinal foot baths, which are of undefined efficacy, will probably have a similar effect. It is possible that some of these products could be considered medicinal by function, but avoid the need for authorisation by vague wording of their efficacy claims. What constitutes a licensed product is also very unclear to the end user, who is often left unaware of the difference and hence unaware of the benefits of using a licensed product.
Annex 11 Participants in the consultation exercise

As reviewed in Section 1.1.5, the options appraisal stage of the study involved an extensive stakeholder consultation exercise, intended to collect evidence as to the implementation and impact of each of the policy options. A summary of the organisations that participated in the various phases of the consultation exercise is shown in below. Details of the four consultation categories are provided in Section 1.1.5.

A11.1 Respondents to policy option survey

A11.1.1 Regulatory bodies:
- The Icelandic Medicines Agency (Iceland)
- Central Agricultural Office Directorate of Veterinary Medicinal Products (Hungary)
- Medical Products Agency (Sweden)
- Agency for Medicinal Products and Medical Devices (Slovenia)
- French Agency for Veterinary Medical Products (France)
- Spanish Medicines Agency (Spain)
- Federal Agency on Medicines and Health Products (Belgium)
- Veterinary Services (Cyprus)
- The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, (Poland)
- Finnish Medicines Agency (Finland)
- Danish Medicines Agency (Denmark)
- Veterinary Medicines Directorate (United Kingdom)
- Norwegian Medicines Agency (Norway)
- The Federal Ministry of Food, Agriculture and Consumer Protection (Germany)

A11.1.2 Industry and industry groups:
- IFAH-Europe
- European Group for Generic Veterinary Products (EGGVP
- Animalcare Group
- Vetoquinol
- Virbac
- Dechra Pharmaceuticals
- Eurovet Animal Health
- Laboratoires Boiron
- Bundesverband für Tiergesundheit (Germany)
- Pharma Industry Finland (Finland)
- Polish Association of Veterinary Drug Producers and Importers (Poland)
- National Office of Animal Health (United Kingdom)

A11.1.3 End user groups:
Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

- Federation of Veterinarians of Europe (FVE)
- Bundestierärztekammer (Germany)
- The Finnish Veterinary Association (Finland)
- The General Association of Romanian Veterinarians (Romania)
- British Veterinary Association (United Kingdom)

A11.2 Attendees of the industry workshop

- IFAH-Europe
- Bayer Animal Health
- HIPRA
- Pfizer Animal Health
- Laboratoire TVM
- Eurovet Animal Health
- Boehringer Ingelheim Animal Health
- European Group for Generic Veterinary Products (EGGVP)
- Laboratoires Boiron
- Novartis
- Merial Animal Health
- Elanco Animal Health
- CEVA Santé Animale
- Laboratorio Maymó

A11.3 Other stakeholder consultation

- Federation of Veterinarians of Europe (FVE)
- European Medicines Agency (EMA)
- Copa-Cogeca

A11.4 Detailed national consultation

A11.4.1 Cyprus:

- Veterinary Services, Ministry of Agriculture, Natural Resources and Environment

A11.4.2 Finland:

- Finnish Medicines Agency (Fimea)
- The Finnish Veterinary Association
- Pharma Industry Finland (PIF)

A11.4.3 Germany:

- The Federal Ministry of Food, Agriculture and Consumer Protection (BMELV)
- Bundesverband für Tiergesundheit (BfT)
- Bundestierärztekammer (BTK)
A11.4.4 Poland:
- Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
- Polish Association of Veterinary Drug Producers and Importers (POLPROWET)

A11.4.5 Romania:
- The General Association of Romanian Veterinarians (AGMVR)

A11.4.6 United Kingdom:
- Veterinary Medicines Directorate
- National Office of Animal Health (NOAH)
- British Veterinary Association
Annex 12 Detailed Appraisal of Policy Options

This Annex consists of a detailed appraisal of the impacts of each of the policy options. An overview of this analysis has been presented in Section 4. For each policy option we provide the following information:

- Presentation of the scores awarded by consultees in respect of the four appraisal criteria outlined above. As set out in Section 1.1.5, stakeholders were asked to rate each option on a scale of -2 to +2, where -2 means ‘significant negative impact’, 0 means no impact, and +2 means ‘significant positive impact’. Results have been disaggregated according to whether stakeholders were representatives of industry, regulators or end user groups (veterinarians and farmers);
- A summary of the comments received from consultees as to the impacts of each of the policy options. Comments were received as part of the detailed engagement carried out in six Member States\(^\text{134}\), and also as part of the material provided through the stakeholder survey;
- If relevant, the results of the SCM for the policy option, and a comparison of the administrative burdens generated by each policy option and the pre-change ‘baseline’ position; and,
- A summary of the key results of the impact assessment, synthesising the available evidence to provide an overview of the impacts of each policy option.

A12.1 Option 1: Extending the scope of the Centralised Procedure

As shown in Table 3.2 on page 31, this policy option consists of 4 sub-options, the impacts of which are reviewed below.

A12.1.1 Sub-option 1.1: The Centralised Procedure becomes mandatory for all products

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.46:

- All respondents reported that this policy option would have a positive impact on the free movement of goods within the EU/EEA;
- Representatives from industry noted that this policy option would have a significant negative impact on administrative burdens (regulators also reported a slight negative impact);
- Industry stakeholders scored this option negatively in terms of its impact on the availability of medicines, as did representatives from regulatory bodies.

\(^{134}\) Cyprus, Finland, Germany, Poland, Romania and the United Kingdom
Figure A12.46 Survey respondents’ scoring of the policy option ‘the Centralised Procedure becomes mandatory for all products’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- The existing committee structure of the Centralised Procedure would cease to operate effectively and efficiently if there was a significant increase in the number of MA applications [regulator];

- MA holders might not want to market their product in all countries (e.g. where diseases are not present in certain climatic zones), and this option would force them to pay for authorisations they had no intention of using [industry];

- Just because a product is authorised does not mean it will be made available, and so there may not be a significant impact on actual product availability [industry];

- The Centralised Procedure is relatively expensive, and SMEs in particular would find it overly burdensome if all applications had to be submitted through the Centralised Procedure [industry];

- Companies often ‘test’ a product in one or perhaps two national markets, then roll it out in ‘waves’ into other countries through the MRP. This staggered approach reduces the risk associated with new product development. Requiring that all products receive their authorisation through the Centralised Procedure would end this mechanism, and does not reflect how the veterinary pharmaceutical market actually operates [industry];

- The cost of the Centralised Procedure would mean that there would probably be a significant decrease in the submission of applications for new MAs (particularly for products where the prospective MA holder only wanted authorisation in a single country and would previously have made use of the National Procedure [industry];

- The protection of human and animal health would be improved due to the high level of expertise within the EMA and the consistent application of standards if all applications were assessed by a single committee [regulator];
This system would create a single market in veterinary medicinal products, and businesses would no longer need to submit multiple versions of a product dossier [industry].

Under this policy option, all applications are submitted through the Centralised Procedure. Administrative burdens can thus be measured by applying the current cost of the Centralised Procedure to all other MA procedures. It is assumed that the total number of applications made each year remains the same. Table A12.7 shows the administrative burdens generated under this policy option, and how they compare to the baseline administrative burdens (as described in Section 2.3).

Table A12.7 The higher cost of the Centralised Procedure relative to the National Procedure means that this policy option increases the total administrative burden imposed on industry by an extra EUR 170.8 million a year

<table>
<thead>
<tr>
<th></th>
<th>Baseline administrative burden (EUR million p.a.)</th>
<th>Policy option administrative burden (EUR million p.a.)</th>
<th>Difference (EUR million p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New MAs</td>
<td>91.1</td>
<td>117.1</td>
<td>26.1</td>
</tr>
<tr>
<td>MA variations</td>
<td>133.5</td>
<td>215.0</td>
<td>81.6</td>
</tr>
<tr>
<td>MA renewals</td>
<td>69.5</td>
<td>132.7</td>
<td>63.2</td>
</tr>
<tr>
<td>Packaging &amp; labelling</td>
<td>184.4</td>
<td>184.4</td>
<td>0.0</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td>59.4</td>
<td>59.4</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>537.9</strong></td>
<td><strong>708.7</strong></td>
<td><strong>170.8</strong></td>
</tr>
</tbody>
</table>

Summary of impact assessment results:

- There was little support amongst consultees and survey respondents for this policy option, despite the fact that it would create a single market for veterinary medicinal products. The main concern expressed by industry representatives was that it would create a significant administrative burden. Businesses wishing to have a product authorised on only a single national market (and data suggest that this is still common) would still be required to have a product authorised in all EU/EEA countries, and bear the burden of translating material into all languages. It was suggested that this would be particularly burdensome for SMEs. Application of the SCM suggests that the administrative burden would indeed increase under this policy option (by an estimated EUR 170.8 million per year).
- Although in principle this policy option would lead to increased availability of medicines, as all new products would be authorised throughout the EU/EEA:
  - Data suggest that just because a product is authorised does not mean that it is actually available, and to increase availability this policy option would need to be combined with, for instance, amendments to packaging and labelling requirements;
  - Business consultees suggested that there would be a significant decrease in new MA applications were the Centralised Procedure to be made compulsory, caused by the high relative cost. This in turn would also affect product availability (particularly in smaller markets where the additional cost would have a more significant impact on the return on investment).
- The process currently followed through the Centralised Procedure would need to be changed were this policy option to be implemented. A number of consultees from all stakeholder groups argued that the EMA would be unable to process the volume of applications that it would receive with its current capacity and procedures.

A12.1.2 Sub-option 1.2: The Centralised Procedure becomes mandatory for all products with new active substances

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.47:
Respondents were largely neutral about the impact of this policy option, reporting that it would have neither a negative or positive effect on most of the impact measures shown below;

Representatives from industry did, however, report that this policy option would have a negative impact on the availability of medicines.

Figure A12.47 Survey respondents’ scoring of the policy option ‘the Centralised Procedure becomes mandatory for all products with new active substances’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Most products with new active substances are already submitted through the Centralised Procedure, and so this policy option would not have a significant impact on the route of submission of MA applications [regulator];
- For safety reasons all innovative products (i.e. including those with new active substances) should be submitted through the Centralised Procedure [regulator];
- Companies should always have the choice as to which countries their products are authorised in; it may not be necessary to have products with new active substances authorised throughout Europe (e.g. due to climatic variations) [industry].

The impact of this policy option on the administrative burden imposed on industry would be negligible, since there would be few products submitted through the Centralised Procedure that would otherwise have been submitted through other procedures. It has thus not been necessary to develop a SCM for this policy option.

Summary of impact assessment results:

- This policy option is expected to have a negligible impact. Consultees and survey respondents generally argued that most products with new active substances are authorised through the Centralised Procedure already.
- Industry representatives suggested that companies should always have the choice as to where...
Assessment of the Impact of the Revision of Veterinary Pharmaceutical Legislation

products were authorised, and thus that the compulsory use of the Centralised Procedure might act as a disincentive to invest. A number of consultees from regulatory bodies, however, suggested that the presence of a new active substance in a product means that a high and consistent level of scientific expertise is needed as part of the assessment process, a role best performed by the EMA.

A12.1.3 Sub-option 1.3: The Centralised Procedure is made available for all products

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.48:

- Stakeholders from industry were generally positive about the impact of this policy option, noting that it would have a minor positive impact on the free movement of goods and the availability of medicines;
- Overall, regulators were largely neutral about the impact of this option.

Figure A12.48 Survey respondents’ scoring of the policy option ‘the Centralised Procedure is made available for all products’

*Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’*

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Opening the Centralised Procedure to all products increases flexibility and choice, and more products would be able to benefit from access to all European markets [industry];
- There might be a small increase in the number of MA applications submitted through the Centralised Procedure if companies were given the choice, but this would be unlikely to affect product types where there are currently gaps in availability, meaning that the impact will be limited [industry];
- The existing committee structure of the Centralised Procedure would cease to operate effectively and efficiently if there was a significant increase in the number of MA applications [regulator].

The impact of this policy option on the administrative burden imposed on industry depends on the number of applications for new MAs, variations to existing MAs, and MA renewals that
would ‘switch’ from the MRP, DCP and National Procedures to the Centralised Procedure. Consultees (see above) argued that the effect would be negligible, and that few businesses would use the Centralised Procedure given the choice. At the industry workshop, attendees suggested that the best proxy indicator of demand would be the number of applications submitted through the MRP and DCP that involved at least 10 countries\textsuperscript{135}. On this basis, Table A12.8 shows the administrative burdens imposed on industry under this policy option.

Table A12.8  The lower cost of the Centralised Procedure compared to the MRP and DCP means that this policy option is estimated to result in savings to administrative burdens worth EUR 5.6 million each year

<table>
<thead>
<tr>
<th></th>
<th>Baseline administrative burden (EUR million p.a.)</th>
<th>Policy option administrative burden (EUR million p.a.)</th>
<th>Difference (EUR million p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New MAs</td>
<td>91.1</td>
<td>88.3</td>
<td>-2.8</td>
</tr>
<tr>
<td>MA variations</td>
<td>133.5</td>
<td>130.6</td>
<td>-2.8</td>
</tr>
<tr>
<td>MA renewals</td>
<td>69.5</td>
<td>69.5</td>
<td>-0.1</td>
</tr>
<tr>
<td>Packaging &amp; labelling</td>
<td>184.4</td>
<td>184.4</td>
<td>0.0</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td>59.4</td>
<td>59.4</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>537.9</strong></td>
<td><strong>532.2</strong></td>
<td><strong>-5.6</strong></td>
</tr>
</tbody>
</table>

Summary of impact assessment results:

- Whilst welcoming the increased flexibility that an extension of the scope of the Centralised Procedure would bring, representatives from industry generally did not expect there to be a significant uptake in the usage of this authorisation procedure. As discussed previously, there is a widespread perception amongst businesses that the Centralised Procedure is relatively expensive and time consuming, and forces businesses to obtain authorisations for countries within which they have no intention of marketing their products.
- It is estimated that the implementation of this policy option would actually result in savings of EUR 5.6 million per year, since SCM data indicate that the MRP and DCP are typically more costly for companies.
- Regulators also noted concerns about the extent to which the EMA would have the capacity to process a large numbers of applications should there be a significant increase in usage of the Centralised Procedure. It was also suggested that the structures in place for the Centralised Procedure – whilst suited to innovative medicines – would not be appropriate for the full range of product types that could potentially be received were the scope of the Centralised Procedure to be extended. These might include relatively well-established medicines that would not require specific scientific expertise.

A12.1.4  Sub-option 1.4: The Centralised Procedure becomes mandatory for all products requiring specific expertise, and is made available for all products

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.49:

- Respondents from industry were largely neutral about the impact of this policy option, reporting that it would have neither a negative or positive effect on most of the impact measures shown below:

\textsuperscript{135} Data show that 71 per cent of applications submitted through the DCP and 39 per cent of applications submitted through the MRP would ‘shift’ to the Centralised Procedure.
Representatives from regulatory bodies awarded minor positive scores for most of the assessment criteria, except for the free movement of goods where a significant positive score was awarded.

Figure A12.49 Survey respondents’ scoring of the policy option ‘the Centralised Procedure becomes mandatory for all products requiring specific expertise, and is made available for all products’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- For the protection of health, the Centralised Procedure should be mandatory for all products that require specific expertise, which the EMA provides consistently [regulator];

- The requirement that all products that require specific expertise be submitted through the Centralised Procedure is largely the situation at present, and thus this option will not have a significant impact [industry];

- Opening the Centralised Procedure to all products increases flexibility and choice, and more products would be able to benefit from access to all European markets [industry];

- There might be a small increase in the number of MA applications submitted through the Centralised Procedure if companies were given the choice, but this would be unlikely to affect product types where there are currently gaps in availability, meaning that the impact will be limited [industry];

- The existing committee structure of the Centralised Procedure would cease to operate effectively and efficiently if there was a significant increase in the number of MA applications [regulator].

As regards the administrative burdens imposed by this policy option, consultees from industry suggested that the requirement that MA applications for products requiring specific expertise be submitted through the Centralised Procedure would have a negligible impact on the distribution of applications across the procedures. Opening the Centralised Procedure to all products might have a minor impact. The methodology followed in this case to develop
the SCM is thus the same as that set out above in Section A12.1.3. The results are shown in Table A12.9.

Table A12.9 The lower cost of the Centralised Procedure compared to the MRP and DCP means that this policy option is estimated to result in savings to administrative burdens worth EUR 5.6 million each year

<table>
<thead>
<tr>
<th>Policy option administrative burden (EUR million p.a.)</th>
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<tr>
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<td>Pharmacovigilance</td>
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<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>537.9</td>
<td>-5.6</td>
</tr>
</tbody>
</table>

Summary of impact assessment results:

- Elements of this policy option are already effectively in place, in that most innovative products (which would require ‘specific expertise’) are already authorised through the Centralised Procedure. Representatives from regulatory bodies largely supported the proposal to make this position mandatory, given the level of scientific expertise within the EMA and the consistent application of this expertise across MAs.
- Industry stakeholders suggested that there would not be a notable increase in the use of the Centralised Procedure if it was extended to all product types. Consequently, the impact on the administrative burden is estimated to be relatively small (a decrease of EUR 5.6 million per year).

A12.2 Option 2: Making a Marketing Authorisation valid throughout the EU/EEA

As shown in Table 3.5 on page 35, this policy option consists of 2 sub-options, the impacts of which are reviewed below.

A12.2.1 Sub-option 2.1: The quality of the work of the competent authorities would be ensured by an independent EU body

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.50:

- Representatives from industry and from end user groups on average awarded a significant positive score across most of the assessment criteria, particularly in respect of the impact on the free movement of goods and the availability of medicines;
- Respondents from regulatory bodies scored this policy option positively in terms of its impact on the free movement of goods, but negatively in terms of its impact on the protection of health.
Figure A12.50 Survey respondents’ scoring of the policy option ‘the quality of the work of the competent authorities would be ensured by an independent EU body’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- This policy option will create a single market and will thus have a substantial impact on the movement of goods and the administrative burden incurred by businesses [industry];
- Just because a product is authorised does not mean it will be made available, and so there may not be a significant impact on actual product availability [end user group];
- Under this policy option, MA assessments are only carried out by a single national authority and there is always a risk that a critical issue will be missed. The Centralised Procedure, MRP and DCP all contain an element of peer review to avoid this reliance on a single authority; without this there is an increased risk to the protection of health [regulator];
- The proposed EU body would benefit from its perceived neutrality and independence, and would build trust in the assessments carried out by competent authorities [regulator];
- The quality assurance systems operated by individual competent authorities may be ‘approved’ by the EU body, but this does not mean that all scientific assessments will be robust, only that quality assurance systems are sufficient [regulator];
- There is a danger that the independent EU body responsible for quality assurance would become another tier of bureaucracy and would lead to delays in the system [industry];
- To be effective the independent EU body would have to have the power to withdraw the right of competent authorities to authorise products if their assessment systems did not meet the necessary standards. This would be politically sensitive [regulator].

As regards the administrative burdens imposed by this policy option, the cost of the Centralised Procedure remains the same as baseline. The MRP and DCP are abolished,
and replaced by what is in effect the National Procedure, in that applicants only need to submit an application to a single national authority. Consequently, estimating the administrative burden associated with this policy option requires ‘shifting’ all applications submitted through the MRP and DCP to the National Procedure. The results are shown in Table A12.10.

Table A12.10 The lower cost of the National Procedure relative to the MRP and DCP means that this policy option results in a saving of EUR 67.9 million per year in administrative burdens

<table>
<thead>
<tr>
<th></th>
<th>Baseline administrative burden (EUR million p.a.)</th>
<th>Policy option administrative burden (EUR million p.a.)</th>
<th>Difference (EUR million p.a.)</th>
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</thead>
<tbody>
<tr>
<td>New MAs</td>
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<td>73.7</td>
<td>-17.4</td>
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<td>MA variations</td>
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<td>-1.4</td>
</tr>
<tr>
<td>Packaging &amp; labelling</td>
<td>184.4</td>
<td>184.4</td>
<td>0.0</td>
</tr>
<tr>
<td>Pharmacovigilence</td>
<td>59.4</td>
<td>59.4</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>537.9</strong></td>
<td><strong>469.9</strong></td>
<td><strong>-67.9</strong></td>
</tr>
</tbody>
</table>

Summary of impact assessment results:

- This option would result in the creation of a single market for veterinary medicinal products, with a single authorisation entitling a company to market their product throughout the EU/EEA. Representatives from industry were strongly in favour of it, as were consultees from end user groups – who expected it to lead to increased availability of medicines.
- The abolition of the need for multiple authorisations for a single product would have a significant effect on the administrative burdens imposed by the legislation, cutting an estimated EUR 67.9 million each year from the admin burdens on the sector.
- Many regulators expressed concern about the devolution of the assessment process to a single country. The key concern, of course, is trust, and the extent to which countries are confident that standards are high enough in all EU/EEA countries to give comfort to others that all authorised products are indeed safe. The proposed independent EU body was seen to provide some assurance that this would be the case, though this body would only be able to assess the quality assurance systems of the organisations that were responsible for carrying out assessments. As several stakeholders noted, the EU body would not be able to ensure the quality of individual MA assessments, which might well vary. Unlike the European procedures currently in use, this policy option does not include any element of peer review which, whilst it requires additional resources and takes time, does provide quality assurance at the level of an individual MA assessment.

A12.2.2 Sub-option 2.2: The quality of the work of the competent authorities would be ensured through a system of accreditation managed by the Member States

The scores awarded by stakeholders as regards the impacts of this policy option are summarised in Figure A12.51:

- Representatives from industry and from end user groups on average awarded a significant positive score across most of the assessment criteria, particularly in respect of the impact on the free movement of goods and the availability of medicines;
- Survey respondents from regulatory bodies awarded significant negative scores in terms of the impacts of this policy option on the protection of human and animal health, and on the administrative burdens imposed on regulators.
Figure A12.51 Survey respondents’ scoring of the policy option ‘the quality of the work of the competent authorities would be ensured through a system of accreditation managed by the Member States’

Average score awarded by stakeholders based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees as regards this policy option were as follows:

- This policy option will create a single market and will thus have a substantial impact on the movement of goods and the administrative burden incurred by businesses [industry];

- Just because a product is authorised does not mean it will be made available, and so there may not be a significant impact on actual product availability [end user group];

- Just because a product is authorised does not mean it will be made available, and so there may not be a significant impact on actual product availability [industry];

- Accreditation of quality assurance systems does not guarantee that each and every scientific assessment will be carried out to the necessary standard, and thus there is a risk that some authorisations by national competent authorities will not be sufficiently robust. The European procedures all contain an element of peer review which is missing under this policy option [regulator];

- Provided the system of accreditation managed by Member States operates in the same way as the current BEMA programme (see Section 3.2.3), this policy option would not create a significant additional administrative burden for competent authorities [regulator];

- The accreditation system would need to be backed by the power to withdraw the right of competent authorities to authorise products if their assessment systems did not meet the necessary standards. This would be politically sensitive [regulator].

The administrative burdens imposed by this policy option are the same as those generated by the previous policy option (see Section A12.2), since the only difference between the two options concerns the design of the quality control system. The administrative burdens imposed by this policy option are shown in Table A12.11.
Table A12.11  The lower cost of the National Procedure relative to the MRP and DCP means that this policy option results in a saving of EUR 67.9 million per year in administrative burdens

<table>
<thead>
<tr>
<th></th>
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</tr>
</tbody>
</table>

Summary of impact assessment results:

- Option 2.2, like Option 2.1, this would create a single market for veterinary medicinal products, and as such is supported by representatives from both industry and end user groups (as it could increase the availability of medicines). The implementation of this policy option would lead to savings in administrative burdens estimated at EUR 67.9 million per year.

- Representatives from regulators – and indeed other stakeholder groups – were largely supportive of this policy option, since it devolves management of the proposed quality assurance system to the Member States (rather than relying on an EU body).

- As with Option 2.1, the key issue is the level of trust between competent authorities, and the extent to which they are willing to accept authorisations carried out by other authorities. Under this option, quality assurance would be provided by a system of accreditation which would ensure that competent authorities met the necessary standards. Member States would manage this system, presumably following the BEMA programme model whereby small teams of individuals from competent authorities carry out visits and assessments of other competent authorities. BEMA is, however, voluntary and aims to share good practice; the accreditation system proposed under this policy option would need to have the power to remove the right to carry out EU/EEA-wide authorisations from Member States that did not meet the agreed standards.

A12.3  Option 3: Improving the operation of current authorisation procedures

As shown in Table 3.6 on page 36, this policy option consists of 3 sub-options, the impacts of which are reviewed below.

A12.3.1  Sub-option 3.1: Voluntary recognition of MAs on a case-by-case basis by competent authorities

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.52:

- Representatives from industry scored this policy option negatively on all four impact assessment criteria;

- On average, regulatory bodies awarded a neutral or slightly positive score, except for the availability of medicines where it was felt that there would be a significant positive impact.

Figure A12.52 Survey respondents’ scoring of the policy option ‘voluntary recognition of MAs on a case-by-case basis by competent authorities’
Average score awarded by survey respondents based on a scale where -2 means 'significant negative impact' and +2 means 'significant positive impact'.

Comments received from consultees and survey respondents as regards this policy option were as follows:

- This policy option is essentially possible under the existing legislation, and is unlikely to make any notable difference [industry, regulator and end user group];
- There would be insufficient transparency of decision-making under this proposal [industry];
- There would continue to be differences in opinion between competent authorities which would restrict the number of products that this would benefit [industry].

This policy option would not have any notable impact on administrative burdens, since companies would still be required to submit applications to each authority. The time taken for authorisations to be granted would decrease, but this would not have a significant effect on administrative burdens, and so the SCM has not been developed for this option.

Summary of impact assessment results:

- This option is not expected to have a significant impact on the problem. It attracted very little support from industry representatives, who suggested that it would not differ substantially from the present situation. It was felt that there would still be differences of opinion between Member States, which would limit the extent to which time savings were achieved. Consultees and survey respondents from regulatory bodies were relatively neutral about this policy option, but again did not feel that it would differ markedly from the present position.
A12.3.2 Sub-option 3.2: Automatic recognition of MAs by competent authorities

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.53:

- Representatives from regulatory bodies suggested that this policy option would have a minor positive impact on administrative burdens, but a significant negative impact on the protection of human and animal health;
- Survey respondents from industry noted that this policy option would have a neutral impact on all four of the impact assessment criteria.

Figure A12.53 Survey respondents’ scoring of the policy option ‘automatic recognition of MAs by competent authorities’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- This option would require competent authorities to automatically accept the results of the assessment made by a single authority, without the possibility to check the quality of the assessment. This poses risks to health protection and would be unacceptable [regulator];
- At present there are frequent differences in opinion between countries, including between authorities in larger countries (who would presumably constitute these groups). As a result it is hard to see how automatic recognition would work [industry];
- Further information is needed on the constitution of these groups of countries, including whether they would be chosen by companies. There is a danger that they would simply involve the largest countries and thus would not solve the problem of availability in smaller countries [end user group];
- This policy option arguably increases the complexity of the MA system, and businesses would need to establish which countries were in which group, and who would be carrying out the actual MA assessment [industry];
If a product was authorised by multiple groups of countries there may not be harmonisation (e.g. groups might insist on differing SPCs) [industry].

This policy option would result in decreases to the administrative burden imposed on industry, since in principle it should be possible for companies to submit a single application to a competent authority. The results of the assessment would then be ‘recognised’ by a semi-formalised group of other competent authorities, without the need for further submissions of material by companies. It is, however, not possible to quantify the effect on the administrative burden, since the number of products that this would apply to, and indeed the number of competent authorities that would participate, is not known and cannot robustly be estimated. We have, therefore, not developed a SCM for this policy option.

Summary of impact assessment results:

- This option creates a single market within limited group(s) of countries who would automatically recognise the assessments made by other group members. Though the composition of these groups would need to be determined, it is reasonable to assume that in practice they would be formed by the countries that participate most frequently within the MRP and DCP. In such cases the costs to businesses of obtaining a MA would be reduced significantly, since a single application would be sufficient for multiple markets.
- The establishment of groups of Member States would require considerable trust between countries (industry representatives raised the current lack of trust as an issue with this policy option). As such, however, this option would probably be less problematic than the policy option which would make authorisations valid in all countries (Option 2), since Member States would be able to restrict this to the countries where they most trusted the capacity and competence of the relevant authorities.
- As noted by industry representatives, however, this option would result in the partial establishment of a single market, and would most likely exclude those countries where the resources committed to authorisation systems were lowest, and whose history of participation in European procedures was shortest. If this were the case, the impact of this policy option on gaps in medicine availability would be limited.
- Regulators also raised concerns about an assessment being carried out by a single authority, with no peer review of the results. It was suggested that this could present a risk to the protection of human and animal health.

A12.3.3 Sub-option 3.3: Improved coordination between competent authorities

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.54:

- Survey respondents from industry and from regulatory bodies awarded this policy option a neutral score in respect of all four impact assessment criteria;
- Representatives from end user groups awarded a minor negative score for all four impact assessment criteria.
Figure A12.54: Survey respondents’ scoring of the policy option ‘improved coordination between competent authorities’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- The major cause of delays within the European procedures is disagreement among competent authorities and improved coordination is not going to address this problem [industry];
- The European procedures have sought to improve coordination among competent authorities since they were introduced and yet there are still delays and inefficiencies; this proposal is unlikely to improve the situation [industry];
- Coordination would need to be managed and there is a danger that this will generate additional administrative burdens for the authorities [regulator].

The purpose of this policy option is to reduce the amount of time required for assessments of MA applications, and to improve the efficiency of the existing systems (so that experts carry out assessments, thus saving time). As such there is no impact on the administrative burdens imposed on industry, as they must still submit the same amount of material. We have, therefore, not developed the SCM for this policy option.

**Summary of impact assessment results:**

- Stakeholders from all groups felt that this policy option would have very little impact. It was noted that the European procedures already involve a certain degree of cooperation between competent authorities, but that this has not significantly reduced the scale of the administrative burden or the time taken for products to be authorised.
- Industry representatives noted that the volume of referrals under the European procedures highlights the frequency with which there are differences of opinion between competent authorities, and that attempts to improve coordination would ultimately have no impact if competent authorities continued to reject the assessments made by others.

**A12.4 Option 4: Simplifying the MA process for low-risk and generic products**
As shown in Table 3.7 on page 36, this policy option consists of 2 sub-options, the impacts of which are reviewed below.

**A12.4.1 Sub-option 4.1: For low-risk/ generic products a fast-track system of authorisation is introduced**

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.55:

- Survey respondents from regulatory bodies suggested that this policy option would have a slightly negative impact on the protection of human and animal health, but would have a minor positive impact on the availability of medicines;
- Overall, industry representatives awarded a negative score for the protection of human and animal health, but strong positive scores in terms of the impact on the free movement of goods and the impact on administrative burdens.

Figure A12.55 Survey respondents’ scoring of the policy option ‘for low-risk/ generic products a fast-track system of authorisation is introduced’

*Average score awarded by survey respondents based on a scale where -2 means ‘significantly negative impact’ and +2 means ‘significantly positive impact’*

Comments received from consultees and survey respondents as regards this policy option were as follows:

- A fast-track system would require additional assessor resources, which are currently unavailable at a national level [regulator];
- Businesses may be willing to pay extra for the use of a fast-track system that enabled them to get their products to market quicker than would otherwise be the case [industry];
- There is a danger that other competent authorities would not accept the results of a fast-track assessment, which could prove a hindrance to the free movement of goods, and would be a problem for generics if this led to competent authorities not recognising an authorisation as a Reference Product [industry];
- A fast-track system increases the risk of unsafe products receiving authorisations [regulator];
▪ There is a risk that this approach will distort the market in favour of generics, which could affect innovation and the development of new products [industry].

This policy option involves the introduction of a fast-track MA application system. As such, therefore, this system will not affect the administrative burdens imposed on businesses (except if a premium were attached to the fast-track system, in which case the costs might actually increase). The benefit will be in reduced decision-making time, meaning that companies would be able to bring a product to market quicker. This will not affect administrative burdens, however, and so we have not calculated a SCM for this policy option.

Summary of impact assessment results:

▪ A number of industry representatives were in favour of a fast-track system whereby an application would be processed quickly in return for a higher fee (since the costs of delays in being able to place a product on the market can outweigh the cost of having a product authorised), but stressed that this option should be open to all products, not just low-risk and generic products.

▪ There was resistance from some industry consultees to any proposal that would further reduce the costs/time taken for the authorisation of a generic product, since it was felt that this would distort the market in favour of generics.

▪ Representatives from regulatory bodies expressed concern about the thoroughness of a fast-track assessment, and the extent to which this might compromise the protection of health. Given these concerns and the current frequency with which there are differences of opinion between Member States, it was also noted by consultees that products authorised through the fast-track system may well face problems where the MA holder seeks to have the authorisation extended into another country, or where the authorisation is used as the reference case for a generic product.

A12.4.2 Sub-option 4.2: For low-risk/ generic products a system of registration replaces authorisations

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.56:

▪ Regulators indicated that this option would have a significant negative impact on human and animal health protection;

▪ All consultees noted that this policy option would have a positive impact on the free movement of goods and administrative burdens;

▪ Industry representatives scored this option negatively in terms of its impact on the availability of medicines.
Figure A12.56 Survey respondents’ scoring of the policy option ‘for low-risk/ generic products a system of registration replaces authorisations’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

| Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users) |
| Comments received from consultees and survey respondents as regards this policy option were as follows: |
| ▪ It is wrong to assume that known active substances are safe; generics and established products can still present a risk to human and animal health. This proposal also ignores the risks posed by quality and variable manufacturing standards [regulator]; |
| ▪ Without harmonisation of Reference Products it would be impossible to set up a registration system for generics [regulator]; |
| ▪ This proposal could distort the market by favouring generics, which could harm innovation and the development of new products [industry]; |
| ▪ This proposal would open the EU/EEA market to products with historical authorisations that do not meet current standards; this could distort the market and make recently authorised products uncompetitive in comparison [industry]; |
| ▪ This policy option would increase the supply of medicines and the level of competition [end user group]. |

This policy option will involve a significant reduction in the administrative burden associated with obtaining a new MA, since the current scientific assessment process will be replaced by a registration system. This option will only apply to low-risk and generic products. The proportion of products that might fall into this category is unknown. Attendees of the industry workshop estimated that around 95 per cent of current products would be likely to be assessed as lower risk. We have, therefore, calculated the SCM for this policy option on the basis that only 5 per cent of product MAs would still require the full scientific assessment each year. The administrative burden associated with the registration exercise has been assumed to be equal to the current cost of applying for a Type 1A variation, since this consists of a relatively simple administrative procedure. The registration procedure will also presumably apply to all subsequent product maintenance requirements, and so the administrative burdens generated by renewals and MA variations have also been reduced.
for the 95 per cent of products adjudged to be lower risk. Again, the cost of a Type 1A variation has been used throughout.

The results of the SCM for this policy option are shown in Table A12.12.

Table A12.12 Under this policy option, the total administrative burdens imposed by the legislation are reduced by EUR 181.9 million per year

<table>
<thead>
<tr>
<th></th>
<th>Baseline administrative burden (EUR million p.a.)</th>
<th>Policy option administrative burden (EUR million p.a.)</th>
<th>Difference (EUR million p.a.)</th>
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<tr>
<td>New MAs</td>
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<td><strong>355.9</strong></td>
<td><strong>-181.9</strong></td>
</tr>
</tbody>
</table>

Summary of impact assessment results:

- There was limited support for this policy option from regulatory bodies who responded to the survey and in consultation. Many regulators were concerned about the impact of this option on the protection of human and animal health, noting that generics products were not necessarily low-risk, and that the full scientific assessment process was a necessary way of ensuring the efficacy and quality of products.
- Industry representatives also expressed concern about the impact of this option on the market. Some argued that it would distort the market in favour of generics and in favour of products that had received authorisations at a time when standards were lower (and thus the assessment was cheaper).
- Despite these concerns this option could reduce administrative burdens imposed on companies by around EUR 181.9 million per year. Regulators would also have a reduced workload under a registration system.
- Representatives from end user groups were more in favour of this policy option since it would probably increase competition and thus lower prices within key product areas. Smaller countries would presumably become more attractive markets if the cost of obtaining an authorisation was reduced significantly.

A12.5 Option 5: Reducing data requirements for authorisations

As shown in Table 3.8 on page 37, this policy option consists of 2 sub-options, the impacts of which are reviewed below.

A12.5.1 Sub-option 5.1: Data requirements for product authorisations are reduced

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.57:

- Survey respondents from industry scored this option positively in terms of its impact on administrative burdens and on the availability of medicines;
- Representatives from regulatory bodies and end user groups also awarded positive scores in respect of the impact of this policy option on administrative burdens and on the availability of medicines, but also gave a significant negative score for the impact on the protection of human and animal health.

Figure A12.57 Survey respondents’ scoring of the policy option ‘data requirements for product authorisations are reduced’
Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Without further information on exactly which data requirements would be removed, it is difficult to assess the impact of this policy option [industry, regulator and end user group];
- It would not be possible to reduce data requirements regarding efficacy and safety without compromising the protection of health [regulator];
- Provided a strong pharmacovigilance system was in place it might be possible to reduce the data submitted during an application for a MA [industry];
- There is scope to reduce the level of administrative data submitted, which adds little yet consumes time and resources, the cost of which gets passed on to the end user [industry];
- Full harmonisation of data requirements between Member States would be more useful, since at present there are numerous additional requests from the authorities, particularly during the European procedures [industry];
- The approach used for products intended for use with MUMS – where reduced data are permitted – could be extrapolated to other product types [industry].

This policy option would reduce the administrative burdens generated when compiling and submitting an application for a new MA, since less data would be required. However, without details of exactly which data requirements would be omitted, it is not possible to measure the impact on the administrative burden through the SCM.
Summary of impact assessment results:

- The data reductions proposed under this policy option were not specified, and consequently consultees and survey respondents were unable to comment in detail on the impacts that might be generated. It was also impossible to measure the impact of this option on administrative burdens.
- Stakeholders agreed that there was scope to reduce administrative data requirements, which were largely seen to be unduly onerous. Most consultees and survey respondents noted that data requirements in the veterinary sector tend to replicate the position for human pharmaceuticals, and that there was scope for reductions given the differences between the two sectors.
- There was no consensus amongst stakeholders as regards whether the amount of efficacy and safety data could be reduced. Representatives from industry wished to see a reduction in the information submitted, arguing that requirements went beyond what was actually needed in order to assess risk, and that there was extensive ‘gold plating’. Most regulators, however, did not support any reductions in data relating to safety, quality and/or efficacy, noting that the approval of medicines had to be based on these criteria.
- A consultee from a regulatory body suggested that safety, quality and/or efficacy data could be reduced provided there was sufficient information to accurately assess the benefit-risk balance of the product. On that model data requirements would vary between product types, and it might be possible to allow reduced data reporting for products deemed to be lower-risk (following the model currently used with MUMS products).
- A number of consultees and survey respondents suggested that there are variations in data requirements between countries, and that this lack of harmonisation increases costs and uncertainties, and acts as a barrier to the free movement of goods.

A12.5.2 Sub-option 5.2: Under certain circumstances products are granted authorisations without the submission of full dossiers

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.58:

- Representatives from end user groups were supportive of this policy option, awarding significant positive scores in respect of its impacts on the availability of medicines and the protection of human and animal health;
- Survey respondents from regulatory bodies awarded significant positive scores in terms of the impact on the availability of medicines and the free movement of goods, but gave a neutral score in terms of the impact on the protection of health.
Figure A12.58 Survey respondents’ scoring of the policy option ‘under certain circumstances products are granted authorisations with the submission of full dossiers’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

▪ In emergency situations this policy option would ensure that medicines were available, particularly in the field of vaccines where there have been problems in the past. There would thus be a positive impact on the protection of human and animal health [end user group];

▪ The benefit-risk assessment is harder without the data included within full dossier submissions, and thus there is an associated increase in risk. It is important that full dossiers are submitted once the emergency need has passed [regulator];

▪ It would be important to ensure that this option was only used in exceptional circumstances, otherwise there is a danger that it might distort competition in the market where products received authorisations based on reduced – and thus less costly – dossiers [industry];

▪ This policy option is largely already present in the current legislation, though it is applied differently between Member States, so harmonisation would be welcome [industry];

▪ Emergency needs can largely be met through the cascade at present, and whilst being used off-label these products have at least been through a full scientific assessment. To grant products authorisations with reduced dossiers risks creating a ‘back-door’ route to the market [industry].

This policy option would significantly reduce the scale of the administrative burden incurred by industry when seeking a MA for a new product, since there would be significant data requirement reductions. However, it is anticipated that this option would only be used in exceptional circumstances, and thus the overall impact on administrative burdens would be negligible, and in any case would depend on the occurrence of epidemic outbreaks. For this reason it has not been possible to measure the impacts of this policy option on the administrative burdens imposed on businesses.
Summary of impact assessment results:

- Most consultees and survey respondents were in favour of this policy option in principle. It could facilitate rapid response to outbreaks of new epidemics, and thus have a significant positive impact on the protection of human and animal health. Whilst the ability to grant authorisations in exceptional circumstances already exists to some extent, this option would harmonise the procedure to be followed, thus reducing uncertainty.
- However, consultees and survey respondents from industry stressed that the circumstances under which reduced dossiers could be submitted should be strictly defined, and that this policy option should not become a way in which companies could bypass the MA process and secure a competitive advantage in the marketplace.

A12.6 Option 6: Simplifying requirements for homeopathic products

As shown in Table 3.9 on page 37, this policy option consists of 2 sub-options, the impacts of which are reviewed below.

A12.6.1 Sub-option 6.1: Homeopathic products are excluded from the scope of the legislation

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.59:

- Respondents from regulatory bodies and industry suggested that this policy option would have a significant negative impact on the protection of human and animal health, though end user groups awarded a strong positive score;
- Stakeholders indicated that this policy option would reduce administrative burdens for homeopathic products.

Figure A12.59 Survey respondents’ scoring of the policy option ‘homeopathic products are excluded from the scope of the legislation’

*Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’*

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:
Any product with a medicinal claim should be included within the scope of the legislation [regulator];

An authority would still need to assess the claims made by homeopathic products, even if this were done outside the scope of the legislation [industry];

Separate legislation for homeopathic products would be beneficial as the current legislative framework is not suitable for such types of medicine [regulator];

Including homeopathic medicines within the scope of the legislation ensures that they must meet efficacy and quality standards. Removing these requirements would open the market to unregulated products with lower production costs, thus creating unfair competition [industry].

This policy option will be associated with a reduction in the administrative burden imposed on those companies responsible for obtaining MAs for homeopathic products. However, though outside the scope of the legislation on veterinary medicinal products, it can be assumed that such products would still need to be regulated, and thus there would still be some administrative burden associated with this process. The number of MAs that would be affected by this policy option is unknown, since the databases provided by the competent authorities did not identify homeopathic products. For this reason it has not been possible to measure the impacts of this policy option on the administrative burdens incurred by businesses.

**Summary of impact assessment results:**

- Opinion was divided on this policy option. Some stakeholders argued that any product making medicinal claims should be treated as a medicine and included within the scope of the legislation. Others argued that the current legislative framework is unsuitable for homeopathic products, which instead need their own legislation.

- A representative of a company that manufactured homeopathic products argued that including such products within the legislation ensured that they meet certain quality standards, and that to remove homeopathic products from the legislation would lower standards within the industry and open the market to competition from low quality products. This would have a negative impact on the protection of health.

A12.6.2 Sub-option 6.2: The registration procedure for homeopathic products is simplified

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.60:

- All stakeholder groups scored this policy option positively in terms of its impact on administrative burdens, and on the free movement of goods;

- There was a consensus amongst respondents that this policy option would have a negative impact on the protection of human and animal health.
Figure A12.60 Survey respondents' scoring of the policy option ‘the registration procedure for homeopathic products is simplified’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

<table>
<thead>
<tr>
<th>Free movement</th>
<th>Admin burdens</th>
<th>Health protection</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
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<td>-1.0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-2.0</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Homeopathic medicines already benefit from a simplified authorisation system, and the removal of any further information requirements (e.g. in relation to quality) might pose a risk to human and animal health protection [regulator];

- Any product intended to be used for the treatment of animal health should be classed as a medicine and thus should be required to meet the same standards; reducing these standards presents a risk to health protection and distorts the market [end user group];

- Homeopathic medicines are known not to have adverse health effects, and thus the requirements as part of the authorisation process should be reduced [industry].

As above, whilst this policy option will reduce the administrative burdens imposed on industry, without data on the scale of the homeopathic product market it is impossible to measure these impacts through the application of the SCM.

Summary of impact assessment results:

- Homeopathic products are already subject to a simplified registration system and are not required to undergo the full scientific assessment process applied to other medicinal products. This policy option would involve a further simplification of this registration scheme, though the details of the simplification would undefined.

- The stakeholders contacted for this study were largely in agreement that, whilst homeopathic products are a special class of product, if they make medicinal claims then they should be treated as medicines. Any further simplification of the requirements should not compromise the principle that medicinal claims must be provable (efficacy), and that quality should be ensured.

- A representative of a company that manufactured homeopathic products supported the simplification of the registration scheme for homeopathic products, arguing that the level of information required for the submission of an application was disproportionate relative to the level of risk involved.
A12.7 Option 7: Enabling the free circulation of authorised products

As shown in Table 3.10 on page 38, this policy option consists of 2 sub-options, the impacts of which are reviewed below.

A12.7.1 Sub-option 7.1: Authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.61:

- Respondents from industry awarded significant positive scores for this policy option in terms of its impact on all four of the impact assessment criteria that were considered;
- Representatives from end user groups also awarded significant positive scores for this policy option;
- Survey respondents from regulatory bodies awarded significant positive scores in respect of the free movement of goods, administrative burdens and the availability of medicines. However, on average regulators also awarded a significant negative score for the impact of this option on the protection of human and animal health.

Figure A12.61: Survey respondents’ scoring of the policy option ‘authorised products with a record of safe use would be allowed to freely circulate throughout the EU/EEA following an administrative assessment’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- If products have been authorised within any EU/EEA country then they are by definition in compliance with the legislation and should be considered safe. This policy option will thus have no negative impact on the protection of human and animal health [industry];
- The principle of veterinary pharmaceutical legislation is that a scientific assessment is made for each country where the product is authorised; the abolition of this process, even for specific circumstances, goes against this principle [regulator];
A ‘record of safe use’ would presumably be based on pharmacovigilance. Pharmacovigilance systems vary between countries and in some cases cannot be relied upon to assess product safety. This is particularly true of older products, where there is significant underreporting by veterinarians of adverse reactions. Moreover, problems may be specific to certain climatic zones, and pharmacovigilance may not accurately reflect the risks involved [regulator];

The absence of problems identified through pharmacovigilance would not be a sufficient measure of safety (in any case products with a problem would probably have had their authorisation revoked). It would also be necessary to take into account the volume of product sales, the volume of prescriptions made, and the number of years a product has been on the market [industry];

Products granted authorisations many years ago would in many cases not meet modern regulatory standards (e.g. missing data). This policy option should only apply to products that were authorised after the introduction of European veterinary pharmaceutical legislation (which could go as far back as 1981, but would more likely be 2001) [regulator];

Clarification is needed on the content of the administrative assessment, since there is a danger that regulators will use this opportunity to request safety, quality and/or efficacy data. The administrative assessment should only consist of verification that Periodic Safety Update Reports have been submitted and assessed [industry];

SPCs will need to be harmonised if this option is to work since the SPC of a product may vary between countries, and only one SPC is possible under this option [regulator];

This option would create problems for regulators who would need to monitor larger numbers of products and could potentially have difficulties in enforcing changes (e.g. to SPCs) where the product was authorised by another authority [regulator];

This policy option will not address the major medicine availability problems since it will only apply to existing products. It may increase competition in larger markets [industry];

The impact of this policy option on the animal health industry would need to be monitored. SMEs focussing on a single national market might be overwhelmed by competition from larger companies, though established products tend to retain market share due to their reputation. Conversely, this policy option might also make expansion into other markets more attractive for SMEs due to the reduced costs and the removal of the need for a ‘daunting’ scientific assessment process. This would probably be particularly true of SMEs that specialise in niche markets (e.g. MUMS uses) [industry];

There is a risk that products authorised according to relatively costly ‘modern’ regulatory standards would be competing against products authorised many years ago when the authorisation process was considerably less expensive. This might distort the market [industry].

This policy option would have a significant impact on the administrative burden imposed on businesses if and when they sought to extend an existing MA to additional countries. At present MA holders have to make use of the MRP in order to do this. The impact of this policy option on the administrative burden can thus partially be estimated by replacing the annual cost of an application for a new MA submitted through the MRP with the cost of an administrative assessment (for the purposes of this calculation assumed to be equivalent to the cost of a Type 1A Variation). This is only a partial estimate since the introduction of this policy option would in all likelihood lead to a significant increase in the number of applications to extend a MA to additional countries.

The resultant change in the administrative burden imposed on businesses is shown in Table A12.13.
Table A12.13 The introduction of an administrative assessment for products with a record of safe use results in a saving in administrative burdens worth EUR 14.2 million per year

<table>
<thead>
<tr>
<th></th>
<th>Baseline administrative burden (EUR million p.a.)</th>
<th>Policy option administrative burden (EUR million p.a.)</th>
<th>Difference (EUR million p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New MAs</td>
<td>91.1</td>
<td>76.9</td>
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<td>MA variations</td>
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<tr>
<td>MA renewals</td>
<td>69.5</td>
<td>69.5</td>
<td>0.0</td>
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<tr>
<td>Packaging &amp; labelling</td>
<td>184.4</td>
<td>184.4</td>
<td>0.0</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td>59.4</td>
<td>59.4</td>
<td>0.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>537.9</strong></td>
<td><strong>523.7</strong></td>
<td><strong>-14.2</strong></td>
</tr>
</tbody>
</table>

Summary of impact assessment results:

- This option would create a single market for established veterinary medicines. Its impact is expected to be significant. It could very quickly address the situation described in Section 2.2.1 whereby a high proportion of veterinary medicinal products are only authorised on a single national market. Market impacts would need to be monitored since this option might expose SMEs to competition from larger companies who were better able to quickly exploit the opportunities created, though the increased competition would be beneficial in the long-term.

- Its effect on product availability is likely to be significant and positive. The range of products available within many product categories would be expected to increase, reducing prices. Smaller markets are likely to become more attractive propositions once the cost of obtaining an authorisation was removed, and thus smaller countries should experience a significant increase in product availability (though the costs of country-specific packaging and labelling would still act as a disincentive). Consultees and survey respondents from industry were largely supportive of this option.

- The administrative burden on industry would decrease substantially as the administrative assessment would replace existing and relatively costly mechanisms for extending MAs to new national markets (e.g. though the MRP). Measuring the scale of the impact is problematic. We have conservatively estimated that were companies able to use an administrative assessment instead of the MRP, then administrative burdens would be reduced by around EUR 14.2 million per year. There is likely to be considerable latent demand for extensions of MAs to additional countries, however, and this option would probably lead to a significant increase in MA applications.

- Set against these benefits are the concerns of most regulators as to the impact of this policy option on the protection of human and animal health. There is, at present, a certain lack of trust amongst competent authorities in the quality of assessment carried out by some other authorities, and in the robustness of pharmacovigilance systems, both of which are key to the implementation of this option. These concerns are particularly acute for ‘higher-risk’ products (potentially including antimicrobials and products authorised many years ago).

- These concerns could potentially be mitigated by restricting the scope of this policy option to an agreed list of ‘lower-risk’ categories of product and/or restricting eligibility to products authorised during the timeframe of EU veterinary pharmaceutical legislation. It may also be necessary to introduce requirements as to the duration/ quality of pharmacovigilance data upon which the record of safe use is based.

A12.7.2 Sub-option 7.2: Systematically harmonise Summaries of Product Characteristics (SPCs) for authorised products

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.62:
▪ Representatives from end user groups awarded a significant positive score in terms of the impact of this policy option on the free movement of goods, the availability of medicines and the protection of human and animal health;

▪ Industry representatives were less positive about this policy option, awarding a significant negative score in terms of the impact on administrative burdens, though a minor positive score on the free movement of goods;

▪ Regulators awarded a significant positive score in respect of the impact on all assessment criteria except for the administrative burdens.

Figure A12.62 Survey respondents' scoring of the policy option ‘systematically harmonise Summaries of Product Characteristics (SPCs) for authorised products’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

▪ The harmonisation of SPCs for all authorised products would require considerable time and effort, and would impose a significant burden on regulators [regulator];

▪ In the short-term this policy option would generate a substantial administrative burden, but in the long-term there would be a significant decrease in the administrative burden imposed on companies. Variations in SPCs between countries create substantial additional packaging and labelling costs, and distort market competition [industry];

▪ Differences in SPCs between countries, for the same product, are difficult for end users to understand and hard to justify on scientific grounds since the same data were used to carry out the authorisation [end user group];

▪ There is a significant danger that the process of SPC harmonisation will lead to the adoption of the ‘lowest common denominator’. Indications that have been authorised for a product for many years may be lost as the initial approval was based on data that would no longer meet requirements (similarly withdrawal periods should not be set at the highest level). This would have a negative impact on the availability of medicines and the protection of human and animal health. Businesses should be able to choose which SPC to use as the ‘reference case’ [industry].
This policy would have an impact on administrative burdens, since companies would no longer have to produce different versions of a product SPC when producing packaging and labelling. The cost incurred by this requirement is, however, not known, and it is impossible to accurately assess how many products are affected by SPC variations, and in how many countries. The process of SPC harmonisation would also presumably be staggered, meaning that it would take many years for the full impact of this policy option on administrative burdens to be realised. For these reasons it has not been possible to develop an SCM for this policy option.

Summary of impact assessment results:

▪ There was a consensus amongst most consultees and survey respondents that this policy option is, in principle, necessary. Variations in SPCs occur when different outcomes have arisen from different regulators’ interrogation of what is in most cases the same data. They are a barrier to the free movement of goods, and impose administrative burdens on businesses (though it has not been able to measure the scale of this burden).

▪ Whilst the principle behind this policy option was widely supported, there were concerns about the detail. The experiences of the CMDv’s ‘pilot’ programme of voluntary SPC harmonisation should be drawn upon in order to establish the basis for the implementation of this policy option. Key issues include:
  o The way in which products are selected for harmonisation (e.g. should this process initially focus on priority products and if so what should they be?); and,
  o The composition and funding of the group responsible for carrying out the harmonisation (and if/ how companies would be able to input into this process and granted the right to challenge any decision made).

▪ The scale of the task means that the process would take many years and consume considerable resources within regulatory bodies and businesses. The number of referrals that presently occur within the European MA procedures highlight the extent to which authorities still disagree over the interpretation of data, and there is a real danger that the systematic harmonisation of SPCs could suffer from paralysis.

▪ Industry has expressed a concern that harmonisation would lead to the loss of indications from SPCs, particularly for older products where data do not meet current requirements (but which were sufficient at the time of authorisation). Reducing indications could negatively impact on the protection of human and animal health. It would be necessary to establish protocols for such situations. These could potentially draw on pharmacovigilance data. Industry representatives recommended that companies should be able to choose a single ‘reference case’ for the SPC harmonisation, though this would be likely to meet resistance from regulators.

A12.8 Option 8: Simplifying pharmacovigilance requirements

As shown in Table 3.11 on page 39, this policy option consists of two sub-options, the impacts of which are reviewed below.

A12.8.1 Sub-option 8.1: Abolish pharmacovigilance requirements

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.63:

▪ Survey respondents awarded this policy option a significant negative score in terms of its impact on the protection of human and animal health;

▪ On average, a positive score was awarded by all categories of respondent in respect of the impact of this policy option on administrative burdens.
Figure A12.63 Survey respondents’ scoring of the policy option ‘abolish pharmacovigilance requirements’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

![Graph showing survey respondents' scoring of the policy option ‘abolish pharmacovigilance requirements’](image)

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- There would be a significant negative impact on the protection of human and animal health, since pharmacovigilance data are essential in order to assess drug safety [regulator];
- Pharmacovigilance data are an important source of information on the development of antimicrobial resistance [regulator];
- This policy option would not present significant risks for human and animal health, since serious incidents would still be detected, and in any case pharmacovigilance systems suffer from underreporting [industry];
- Whilst this policy option would reduce administrative burdens in the short-term, there is a danger that the benefits would be outweighed by increases in legal costs due to product complaints [industry];
- There is a danger that, without pharmacovigilance data, the authorities would adopt a more conservative approach towards assessing MA applications, resulting in an increase the volume of safety data required [industry];
- Since Europe is a member of VICH, industry would still have pharmacovigilance obligations for third country reporting to the United States and Japan [industry].

Under this policy option, the administrative burden generated through pharmacovigilance is reduced to zero (see Table A12.14).

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136 VICH is a trilateral (EU-Japan-USA) programme aimed at harmonising technical requirements for veterinary product registration, including requirements in relation to pharmacovigilance
Table A12.14  The abolition of pharmacovigilance results in a saving in administrative burdens worth EUR 59.4 million per year

<table>
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<th>Baseline administrative burden (EUR million p.a.)</th>
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<td>MA variations</td>
<td>133.5</td>
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<tr>
<td>MA renewals</td>
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<td>69.5</td>
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<tr>
<td>Packaging &amp; labelling</td>
<td>184.4</td>
<td>184.4</td>
<td>0.0</td>
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<tr>
<td>Pharmacovigilance</td>
<td>59.4</td>
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<td>-59.4</td>
</tr>
<tr>
<td>Total</td>
<td>537.9</td>
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<td>-59.4</td>
</tr>
</tbody>
</table>

Summary of impact assessment results:

- This option is not regarded as prudent. Pharmacovigilance data are essential for monitoring the safety of a product once it has been authorised, and there are frequently cases where product SPCs are changed based on how they perform once placed on the market. Consultees and survey respondents, particularly those from regulatory bodies, were almost all opposed to the option. Regulatory bodies warned of significant negative impacts on the protection of human and animal health.

- Representatives from industry, whilst supportive of the abolition of a significant administrative burden (savings are estimated to amount to EUR 59.4 million per year), were concerned that a reliance on liability could lead to increased legal costs due to complaints. It was also noted that this option would bring Europe out of line with other VICH markets (the United States and Japan).

A12.8.2  Sub-option 8.2: Simplify pharmacovigilance requirements

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.64:

- All three stakeholder groups awarded a significant positive score in terms of the impact of this policy option on administrative burdens;

- Consultees from industry awarded a neutral score in terms of the impact of this policy option on the protection of human and animal health, but representatives from regulatory bodies and end user groups awarded a negative score;

- Representatives from industry indicated that this policy option would have a positive effect on the availability of medicines.
Figure A12.64: Survey respondents’ scoring of the policy option ‘simplify pharmacovigilance requirements’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

<table>
<thead>
<tr>
<th>Base</th>
<th>Industry responses</th>
<th>Regulators responses</th>
<th>End user responses</th>
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</thead>
<tbody>
<tr>
<td>12</td>
<td>14</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Whilst this policy option would allow regulators and industry to focus resources on priority issues, access to robust pharmacovigilance information is key to the protection of human and animal health [regulator];
- The efficacy data provided within PSURs can be an indicator of the development of resistance (e.g. to antimicrobials) and should not be abolished [regulator];
- This policy option would lead to a significant reduction in administrative burdens, for instance industry would no longer have to submit multiple variations each time a minor change is made to a company’s pharmacovigilance system [industry];
- Current pharmacovigilance requirements have been based on the human medicine system, which is too onerous for the animal health industry, and is not necessary given the lower level of risk involved [industry];
- Established and generic products are less risky and thus a reduction of pharmacovigilance requirements would have no impact on the protection of human and animal health [industry];
- If PSURs were retained, this policy option should include the option to issue product PSURs on a single EU/EEA wide date, since variations in ‘birthdates’ between countries mean that multiple PSUR submissions are often required [industry];
- A simplification of pharmacovigilance requirements would encourage veterinarians to report more consistently, and would thus improve the quality of the data [end user group].

This policy option will involve the reduction of pharmacovigilance requirements. It is reasonable to assume that this will not apply to the reporting of suspected adverse reaction and serious adverse reaction data, since companies would presumably always need to keep the authorities informed of such incidents. Instead, it has been assumed that simplification...
involves the abolition of requirements to submit PSURs. The resultant change in the administrative burden imposed on businesses is shown in Table A12.15.

**Table A12.15**  The simplification of pharmacovigilance results in a saving in administrative burdens worth EUR 47.2 million per year

<table>
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<th>Baseline administrative burden (EUR million p.a.)</th>
<th>Policy option administrative burden (EUR million p.a.)</th>
<th>Difference (EUR million p.a.)</th>
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<td>New MAs</td>
<td>91.1</td>
<td>91.1</td>
<td>0.0</td>
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<td>MA variations</td>
<td>133.5</td>
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<td>MA renewals</td>
<td>69.5</td>
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<td>Packaging &amp; labelling</td>
<td>184.4</td>
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<td>Pharmacovigilance</td>
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<td><strong>490.7</strong></td>
<td><strong>-47.2</strong></td>
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</table>

**Summary of impact assessment results:**

- This option is popular and viable, though there is further work to be done as regards the details of the proposal. There was a broad consensus amongst consultees and survey respondents from across all stakeholder categories that a simplification of pharmacovigilance requirements is necessary. The current system is based on the system for human medicines, and there is widespread view that the equivalent level of investment is not justified in animal health. With some exceptions, the benefit of collecting pharmacovigilance data for products that had been marketed for decades was seen to be negligible by most consultees.

- Industry has argued that the administrative burden associated with meeting pharmacovigilance requirements is prohibitively high (the implementation of this policy option would save an estimated EUR 47.2 million per year). Regulators – particularly those from smaller countries where there may only be a small number of employees – have argued that processing pharmacovigilance submissions consumes too much time and effort.

- Whilst supportive of the simplification of pharmacovigilance, regulatory bodies wished to retain the current system for certain categories of product. This included products deemed to be ‘higher-risk’ (e.g. potentially including antimicrobials), and also products based on a new active ingredient.

- There is a general belief amongst stakeholders that adverse reactions to medicines are under-reported, particularly by veterinarians. It was suggested that this issue related mainly to the reporting of adverse reactions for older products where such adverse reactions are well known and veterinarians thus did not see the need to provide such information. It was also suggested that there is insufficient detailed feedback from the pharmacovigilance system, which discouraged veterinarians from taking the time to submit information. Overall, therefore, there is a belief amongst many stakeholders that the current pharmacovigilance system is not fit for purpose. A simplification of the system, it was suggested, might encourage improved reporting.

**A12.9 Option 9: Simplifying requirements for renewing Marketing Authorisations**

As shown in Table 3.12 on page 39, this policy option consists of 2 sub-options, the impacts of which are reviewed below.

**A12.9.1 Sub-option 9.1: Abolish the requirement to renew a MA**

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.65:

- Survey respondents indicated that this policy option would have a significant positive impact on administrative burdens, and a minor positive impact on the availability of medicines;
Representatives of end user organisations and industry did not feel that this option would have a negative impact on the protection of human and animal health, but regulators awarded a significant negative score.

Figure A12.65 Survey respondents’ scoring of the policy option ‘abolish the requirement to renew a MA’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- PSURs are now the main way in which information about post-authorisation safety, quality and efficacy performance is collected, and so the lack of MA renewals would not have a significant impact [regulator];
- Renewals provide an opportunity for the authorities to require the details of a MA to be changed, or even withdrawn. If renewals are removed it will be necessary to strengthen the legal basis to perform these actions based on pharmacovigilance information [regulator];
- The renewal process requires MA holders to submit data on quality and efficacy that they do not need to submit through pharmacovigilance; renewals thus provide the authorities with an important source of product information [regulator];
- Removing renewals for new and novel products would present a risk to human and animal health [regulator].

Under this policy option, the administrative burden generated through the renewal of MAs is reduced to zero (see Table A12.16).
Table A12.16 The abolition of the requirement to renew a MA results in a saving in administrative burdens worth EUR 69.5 million per year

<table>
<thead>
<tr>
<th></th>
<th>Baseline administrative burden (EUR million p.a.)</th>
<th>Policy option administrative burden (EUR million p.a.)</th>
<th>Difference (EUR million p.a.)</th>
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</thead>
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<tr>
<td>New MAs</td>
<td>91.1</td>
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<td>MA renewals</td>
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<tr>
<td>Packaging &amp; labelling</td>
<td>184.4</td>
<td>184.4</td>
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<tr>
<td>Pharmacovigilance</td>
<td>59.4</td>
<td>59.4</td>
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<td><strong>Total</strong></td>
<td><strong>537.9</strong></td>
<td><strong>468.3</strong></td>
<td><strong>-69.5</strong></td>
</tr>
</tbody>
</table>

Summary of impact assessment results:

- This option delivers significant administrative burden savings (an estimated EUR 69.5 million per year) but would involve regulators losing what they see as a useful opportunity to adjust authorisation details.
- There was limited support amongst regulators for the complete abolition of MA renewals, as they are seen to provide an opportunity to undertake a much more thorough review of a product post-authorisation than is the case based on a review of pharmacovigilance data. Consultees noted instances where the renewal of a MA had presented an opportunity to have an authorisation changed based on the product’s performance in the market, an amendment that would not have been triggered by pharmacovigilance data alone. Industry, on the other hand, was supportive of the abolition of renewals, which constitute a considerable administrative burden.

A12.9.2 Sub-option 9.2: Restrict the requirement to renew a MA to specific cases based on the risk profile of the product

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.66:

- There was a consensus amongst survey respondents that this policy option would have a significant positive impact on administrative burdens;
- Regulators awarded a negative score in terms of the impact of this policy option on the protection of human and animal health, though the two other stakeholder categories on average awarded a minor positive score.
Figure A12.6 Survey respondents’ scoring of the policy option ‘restrict the requirement to renew a MA to specific cases based on the risk profile of the product’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- A harmonised approach is essential, otherwise some countries would require a renewal, whilst others would not, thus adding complexity and generating administrative burdens [industry];
- A harmonised approach between countries would be difficult since the risk profile may vary between countries (e.g. due to climatic differences) [regulator];
- The criteria used to assess the level of risk will be critical, and there is a danger that some countries will continue to require renewals for the majority of products [industry].

Under this policy option, the requirement to renew a MA is removed except for products that the competent authorities judge to present a risk. The proportion of products that might fall into this category is unknown. Attendees of the industry workshop estimated that around 95 per cent of current products would be likely to be assessed as lower risk. We have, therefore, calculated the SCM for this policy option on the basis that only 5 per cent of product MAs would need to be renewed. The results are shown in Table A12.17.
Table A12.17  Restricting the requirement to renew a MA to higher risk products results in a saving in administrative burdens worth EUR 67.5 million per year

<table>
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<th>Baseline administrative burden (EUR p.a.)</th>
<th>Policy option administrative burden (EUR p.a.)</th>
<th>Difference (EUR p.a.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New MAs</td>
<td>91.1</td>
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<tr>
<td>MA variations</td>
<td>133.5</td>
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<td>Packaging &amp; labelling</td>
<td>184.4</td>
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</tr>
<tr>
<td>Pharmacovigilance</td>
<td>59.4</td>
<td>59.4</td>
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</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>537.9</strong></td>
<td><strong>470.3</strong></td>
<td><strong>-67.5</strong></td>
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</tbody>
</table>

Summary of impact assessment results:

- This option is, for regulators, a more palatable option because requires a renewal procedure for higher-risk products and still delivers significant admin burden savings to industry. An EU-wide framework for the determination of the risk profile of products would be required to ensure consistency. This could potentially be the same framework used to support other sub-options, such as Options 4 and 7).
- Regulators were, for the most part, more supportive of the restriction in the use of renewals than they were of their complete abolition. Industry was enthusiastic about the potential reduction in the administrative burden that would result from this policy option (annual savings could be worth up to EUR 67.5 million, assuming that the majority of products – industry representatives believed the figure to be 95 per cent of products – would be classed as lower-risk), but expressed concerns about how it would be implemented. Specifically, it was noted that the renewal requirement should be applied (or not applied) consistently, rather than one country requiring a renewal and another not (though regulators noted that the risk profile of a product might change between countries).

A12.10  Option 10: Simplifying data recording and reporting requirements

As shown in Table 3.13 on page 39, this policy option consists of 1 sub-option, the impacts of which are reviewed below.

A12.10.1  Sub-option 10.1: The amount of data that must be recorded and reported is reduced

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.67:

- All stakeholder groups scored this option positively in terms of its impact on administrative burdens;
- Both regulators and end user groups awarded a significant negative score in respect of the impact of this option on the protection of human and animal health.
Figure A12.67 Survey respondents’ scoring of the policy option ‘the amount of data that must be recorded and reported is reduced’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Without further information on the data that will be affected it is impossible to comment on the impacts of this policy option [industry, regulator and end user group];
- Any reduction in data reporting is welcome, and a decrease in the scale of the administrative burden would result in additional investment in new product development [industry];
- Data recording and reporting requirements for veterinarians are presently not problematic and do not provide an undue administrative burden [end user group].

This policy option would reduce the administrative burdens generated by stakeholders within the veterinary medicinal products supply chain, since less data would be required. However, without details of exactly which data requirements would be omitted, it is not possible to measure the impact on the administrative burden through the SCM.

Summary of impact assessment results:

- Without additional detail on the identity of the data recording and reporting requirements that would be reduced, stakeholders were unable to comment on the proposal. It was assumed by most survey respondents that this policy option would reduce the scale of the administrative burden (though this decrease could not be measured).
- It can be assumed that this policy option will apply to the veterinary medicine supply chain, since reductions in data requirements as part of the product authorisation process form part of other policy options. Only veterinarians were included within the consultation exercise carried out for this study, and consultees and survey respondents did not believe that there were any significant unnecessary data recording and reporting requirements at present.
A12.11 Option 11: Simplifying packaging and labelling requirements

As shown in Table 3.14 on page 40, this policy option consists of 3 sub-options, the impacts of which are reviewed below.

A12.11.1 Sub-option 11.1: Prior approval of packaging and labelling by the authorities is abolished

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.68:

- Survey respondents from industry awarded a significant positive score in relation to the impact of this policy option on administrative burdens, and a minor positive score in respect of the impact on the free movement of goods. A neutral score was given for the impact of this option on the two other assessment criteria;
- Stakeholders from regulatory bodies awarded positive scores in relation to the impact on administrative burdens and the availability of medicines, but gave a significant negative score in terms of the impact on the protection of human and animal health;
- Representatives from end user groups awarded positive scores in respect of all four impact assessment criteria, including significant positive scores in relation to the impact on the free movement of goods and the availability of medicines.

Figure A12.68: Survey respondents’ scoring of the policy option ‘prior approval of packaging and labelling by the authorities is abolished’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- A high error rate is seen when packaging and labelling text is checked, meaning that without prior approval there would be products in the market that did not comply with packaging and labelling requirements [regulator];
- It is important that end users know that products on the market comply with the legislation, otherwise there is a risk to the protection of health [end user group];
• Where non-compliant products were found on the market, a difficult decision would need to be made as to whether the infringement was serious enough to warrant a recall, and there would need to be a firm legal basis for this decision [regulator];

• The damage to a company’s/ product’s reputation caused by a recall due to a packaging and labelling error would be substantial. Companies have a strong incentive to comply with the legislation, and should be trusted to do so [industry];

• Were recalls needed this would have a significant negative impact on availability, and would damage the reputation of regulators and industry — it is better to ensure that packaging and labelling is correct before products enter the market, in order to preserve end user confidence in the system [regulator];

• The implementation of this policy option would require an increase in in-market checks. Many countries will not have the resources available for such checks, and without this there is a danger that non-compliant products will enter the market [regulator];

• This policy option would reduce the costs of product authorisation significantly, and would end the delays caused by ‘toing-and-froing’ between companies and competent authorities as packaging and labelling text is checked and corrections requested. This is particularly true of multilingual labelling which must be approved by all the authorities concerned. If one country requests a change then this in turn has to be approved by all authorities [industry];

• Variations between countries as to the required content of packaging and labelling are a major burden for industry, and it is at the pre-authorisation stage that these problems arise. Removing prior approval of packaging and labelling would reduce the scope of competent authorities to request country-specific amendments, thus reducing the costs imposed on businesses [industry].

This policy option would reduce the cost of applying for a new MA, since the requirement to include mock-ups within the application would be removed. The cost of applying for a variation to an existing MA and the cost of renewing a MA would be unaffected. It was not possible to disaggregate the estimate of packaging and labelling costs within the SCM into its component parts. We have not, therefore, been able to calculate the costs of producing and submitting mock-ups, and thus cannot estimate the impact of this policy option on the administrative burdens imposed on industry.

Summary of impact assessment results:

• There was a clear divide as regards this policy option, with representatives from industry largely in favour of its implementation, and representatives from regulatory bodies largely against its introduction. From an industry perspective it was felt that prior approval of packaging and labelling generates an administrative burden (though it has not been possible to quantify the scale of this burden) and imposes delays, and provides competent authorities with an opportunity to impose country-specific packaging and labelling requirements.

• Regulators, conversely, stressed that prior approval of packaging and labelling provides an opportunity to ensure compliance with the legislation before products are placed on the market and thus help to protect human and animal health. Regulators cited frequent instances of non-compliance, and stated that without prior approval these products would have had to be recalled from the market at considerable cost to industry (though in practice the financial cost of such recalls, together with the impact on a company’s reputation, would presumably mean that MA holders would be more careful about compliance). Regulators also noted that the scale of in-market checks would need to be increased significantly in order to ensure compliance.

• Consultations with Member States indicates that some countries – particularly smaller Member States – waive the requirement for prior approval of packaging and labelling since they do not have the resources to carry out such assessments.

A12.11.2 Sub-option 11.2: The amount of text required on packaging and labelling is reduced
The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.69:

- Representatives from industry and end user groups both awarded significant positive scores to this policy option, particularly as regards its impact on administrative burdens;

- Survey respondents from regulatory bodies gave a significant negative score to this option in relation to its impact on the protection of human and animal health.

Figure A12.69 Survey respondents’ scoring of the policy option ‘the amount of text required on packaging and labelling is reduced’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Reducing the amount of text required on packaging and labelling would make it feasible for companies to market medicines in smaller countries where the costs of producing small batches are presently prohibitive [industry];

- Obligatory font sizes should also be abolished since this poses problems for certain types of packaging [industry];

- If pictograms were used then a harmonised ‘library’ of images would need to be developed and agreed. Whilst this should be possible, there would be difficulties in establishing images that would be recognised by end users in all countries without risk of misinterpretation [industry];

- To avoid confusion, leaflets should always contain the same information that is displayed through pictograms [regulator];

- It should be possible to reduce the amount of text required on outer packaging without compromising the protection of health, but no reductions should be made to the text within leaflets, which provides essential safety information [regulator];

- For some forms of packaging (e.g. sachets), leaflets can be a particular problem, and attention should also be given to reducing the information that must be provided on leaflets [industry];
Reductions in the amount of text and information that accompanies products would be acceptable, but only if this were counterbalanced by other information sources. This might include a detailed drug compendium available to veterinarians, and/or barcodes on products which contain detailed information that veterinarians could scan and access [end user group].

This policy option will have a significant impact on the administrative burden imposed on industry, since the results of the SCM show that the costs of packaging and labelling are one of the major administrative burdens, and this option would lead to a significant reduction in the amount of information required. However, without more detail of the amount of text that would be reduced, and where this would apply (e.g. outer packaging, leaflets etc), it has not been possible to quantify the scale of the impact on administrative burdens.

Summary of impact assessment results:

- This option is popular in principle but the challenge lies in finding ways to achieve the reduction in text while satisfying concerns about clarity and interpretation and provision of complementary sources of information.
- Representatives from industry were in favour of this policy option, noting that reductions in packaging and labelling text would result in a significant decrease in administrative burdens (though it has not been possible to quantify the scale of this burden), and would make it feasible to market products in smaller countries, thus increasing availability. Regulators were also generally in favour of this policy option, with the proviso that reductions in text did not compromise the protection of health. For this reason it was stressed that the information contained in leaflets should not be reduced, and that any abbreviations and pictograms that were used would need to be carefully designed and agreed throughout the EU/EEA.
- Consultees from end user groups were also in favour of reductions in packaging and labelling text since this would increase the availability of medicines. However, it was also suggested that any reductions in the text contained on/in individual products should be counterbalanced by improvements in alternative sources of information, such as drug compendia and/or product barcodes.

A12.11.3 Sub-option 11.3: The authorities may authorise the use of non-official languages

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.70:

- Representatives from industry and end user groups both awarded significant positive scores to this policy option, particularly as regards its impact on administrative burdens;
- Survey respondents from regulatory bodies gave a significant negative score to this option in relation to its impact on the protection of human and animal health.
Figure A12.70 Survey respondents’ scoring of the policy option ‘the authorities may authorise the use of non-official languages’

*Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’*

<table>
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<th>Free movement</th>
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<th>Admin burdens</th>
<th>Availability</th>
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<tr>
<td>End users</td>
<td></td>
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</tr>
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</table>

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- This option would be of significant benefit in smaller countries (where it would put into law the approach that many authorities take in any case), and would increase the range of product available [regulator];

- There may be an issue for the protection of health where products are labelled in non-native languages. For the most part veterinarians will probably speak one of the major European languages, but this may not be the case for end users [regulator];

- In some countries it may not be possible for legal reasons to permit packaging and labelling to be presented in non-official languages, regardless of whether this was allowed by veterinary medicinal products legislation [regulator].

This policy option will have a significant impact on the administrative burden imposed on industry, since the costs incurred by producing packaging and labelling in multiple languages are significant (and are a key barrier to the marketing of products in smaller countries). This policy option would result in a decrease in administrative burdens within countries that chose to make use of the flexibility granted. The identity of these countries, of course, is not known, and in any case the option may not be used for all product types. Consequently we have not been able to quantify the impact on administrative burdens of this policy option.

**Summary of impact assessment results:**

- This option provides national authorities with the option of allowing marketing of products labelled in languages other than their Member State’s official languages. It could help improve the economics of serving small markets but authorities would need to assess the potential risks of non-expert end users not being able to understand the label.

- Industry representatives suggested that this policy option would decrease administrative burdens (though it has not been possible to quantify the scale of this burden) and make it feasible to market products within smaller countries, since packaging and labelling could be produced in
A12.12 Option 12: Simplifying requirements for applying for variations to MAs

As shown in Table 3.15 on page 41, this policy option consists of 1 sub-option, the impacts of which are reviewed below.

A12.12.1 Sub-option 12.1: Simplifying variations requirements

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.71:

- Representatives from industry awarded significant positive scores for all four impact assessment criteria, particularly for the impact that this policy option would have on administrative burdens;
- Regulators gave a positive score in respect of the impact of this option on administrative burdens, but a significant negative score in terms of the impact on the protection of human and animal health.

Figure A12.71 Survey respondents’ scoring of the policy option ‘simplifying variations requirements’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- This policy option would significantly reduce the time and resources consumed within both industry and regulatory bodies submitting and processing administrative data, and allow such resources to be spent on more important tasks [industry and regulator];
To some extent the new variations legislation introduced this option, though take-up has so far been low since companies frequently do not understand when they are permitted to group submissions (see Section 3.2.13) [industry];

It is essential that authorities are informed of any changes to the MA. Companies should not be allowed to make changes and not inform the authorities in a timely fashion, or this option could present a risk to the protection of health [regulator];

This policy option could present a risk to the protection of health. In emergency situations the competent authorities need to be sure that they have up-to-date contact information, and there is a risk that some businesses might not update this information if requirements were relaxed [regulator];

The types of variations for which simplification will be permitted is critical if this option is to have any impact. For immunological products, for instance, almost all variations are typically considered to be Type 2 variations [industry].

In principle, under this policy option MA holders will not be required to submit applications for Type 1A variations to the authorities. Type 1B and Type 2 variations are not affected under current proposals. MA holders will still need to compile the information required for a Type 1A variation, but will not need to submit this material. Table A12.18 presents the results of the SCM that has been developed for this policy option.

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<th>Difference (EUR million p.a.)</th>
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<td>Packaging &amp; labelling</td>
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</table>

Summary of impact assessment results:

- With further development, this option could deliver savings in administrative burdens. Further work would be needed on how to simplify current arrangements whilst ensuring that competent authorities are notified of administrative adjustments to the MA.
- Whilst supportive of the goal to reduce administrative burdens, consultees and survey respondents from regulatory bodies raised concerns about the impacts that this policy option could have on the protection of human and animal health. Their expectation was that the authorities should always be informed of any changes to a MA, and that this requirement should be retained even if MA holders were permitted to actually make the changes themselves. Increased usage of electronic communication methods could enable MA holders to keep competent authorities informed of any changes without recourse to the submission of paper versions of variations.
- Businesses were in favour of this policy option, noting that it would reduce administrative burdens in an area that they do not feel contributes significantly to the protection of health.
- The savings to the administrative burden incurred by industry is estimated to be around EUR 10.9 million per year, but the exact value of the reduction will depend on which types of variation are included within the simplification exercise (for the development of the SCM we have assumed that it applies only to Type 1A variations).
A12.13  Option 13: Amending the scope of the cascade

As shown in Table 3.16 on page 41, this policy option consists of 3 sub-options, the impacts of which are reviewed below.

A12.13.1  Sub-option 13.1: Abolish the cascade

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.72:

- Representatives from end user groups and regulatory bodies awarded a significant negative score with respect to the impact of this policy option on the availability of medicines;
- On average, all stakeholder groups awarded a significant negative score in terms of the impact of this policy option on the protection of human and animal health.

Figure A12.72 Survey respondents’ scoring of the policy option ‘abolish the cascade’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Abolishing the cascade would have a highly detrimental impact on animal welfare since veterinarians would be unable to treat many conditions. This in turn could negatively affect human health [regulator, industry and end user group];
- It will never be the case that there will be an authorised medicine available for all conditions in all animals in all countries, so the cascade will always be needed to some extent. Some markets are simply too small for companies to invest in developing products, regardless of how far regulatory costs are reduced [end user group];
- Enforcing this proposal would be impossible, and would in practice vary between Member States [regulator];
- This policy option would encourage the illegal usage of veterinary medicinal products, which since this would take place outside of regulatory control would be less safe than using the cascade [regulator].
This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- There was no support for this policy option amongst consultees or survey respondents. End user groups expressed particular concern that this option would have a highly detrimental impact on animal welfare, and would encourage the illegal and unregulated usage of veterinary and human medicinal products. Veterinarians argued that the cascade will always be a key provision in the treatment of animals, since there will never be universal availability of medicines.
- Representatives from industry, who might, potentially, benefit from a removal of the cascade (the over- and illegal use of which might act as a disincentive to invest in new medicines), were not supportive of this option due to animal welfare concerns. They noted that regulatory costs are a more significant disincentive for investment than the usage of the cascade.

A12.13.2 Sub-option 13.2: Reduce the scope of the cascade

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.73:

- Survey respondents from end user groups awarded a significant negative score in respect of the impact of this policy option on the protection of human and animal health, and a minor negative score in respect of the impact on the availability of medicines;
- Representatives of regulatory bodies also awarded a negative score in terms of the impact on the protection of human and animal health.

Figure A12.73 Survey respondents’ scoring of the policy option ‘reduce the scope of the cascade’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- The order of the cascade should be changed so that the usage of medicines authorised for use in humans appears below the usage of veterinary medicines authorised in
another European country. The use of human medicines is far more of a health risk than the use of veterinary medicines [end user group];

- Moving the current third tier of the cascade (products authorised for use in other countries) above the usage of human medicines would cause practical problems since veterinarians would not know exactly what was available in other countries, and would need to import such medicines (which would not be practical where a condition needed to be treated immediately) [industry];

- It may be necessary to restrict the usage of the cascade amongst food-producing species, since this poses a greater risk to human health [end user group];

- The usage of medicines authorised for use with humans through the cascade is problematic, since it may be done on cost grounds even where an authorised medicine is available. There is also no information on dosage etc. available for human medicines, and the manufacturer of a human medicine is unlikely to provide any support to a veterinarian seeking to use the product on an animal [regulator];

- Statutory withdrawal periods should be introduced and harmonised across all countries, and the minimum withdrawal periods currently contained in the legislation should be revised so that they fit with animal lifetimes [end user group];

- The key problem with the cascade is not how it is regulated within the legislation, but the variations between countries in how the legislation is enforced, such that some countries are very restrictive, whilst others permit almost any usage of the cascade [regulator].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

### Summary of impact assessment results:

- Whilst the way in which usage of the cascade would be restricted was not defined, there was some support amongst consultees for reordering the order of the cascade, such that the usage of human medicines become the last possible option. It was noted, however, that this would present practical problems, and it may be necessary to caveat this reordering such that in cases where immediate treatment is needed, human medicines could be used before medicines authorised in other countries.

- There was little support for this policy option from the industry, despite the fact that the over- and illegal use of the cascade could potentially act as a disincentive for the development of new medicines. Other factors were seen as more important when seeking to remove barriers to investment.

- Many stakeholders argued that the cascade is already sufficiently restrictive, and that the suspected problem of overuse was a result of insufficient enforcement, which would not be solved by the introduction into the legislation of further reductions in scope.

### A12.13.3 Sub-option 13.3: Increase the scope of the cascade

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.74:

- Survey respondents from end user groups awarded a minor positive score as regards the impact of this policy option on the free movement of goods, and a significant positive score as regards the impact on the availability of medicines;

- Representatives from industry and from regulatory bodies both awarded a significant negative score in terms of the impact of this option on the protection of human and animal health, whilst survey respondents from end user groups awarded a minor negative score.
Figure A12.74 Survey respondents’ scoring of the policy option ‘increase the scope of the cascade’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

-2.0
-1.0
0.0
1.0
2.0
Free movement
Health protection
Admin burdens
Availability

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Restrictions on the usage of the cascade should be relaxed for minor species and for companion animals, since the risk to human health is much lower than it is for food-producing species [end user group];

- For companion animals where the risks are lower, where there are no authorised veterinary medicines available to a veterinarian the cascade should be extended to permit the importation and usage of human medicines from within the EU/EEA, and the importation and usage of veterinary medicines from selected third countries (e.g. the United States). This would improve the protection of human and animal health [end user group];

- The impact would be negligible since in practice the usage of the cascade is largely unchecked; this option would simply legalise what we suspect is already the case [regulator];

- Enabling the usage of human medicines within animals, for instance, would negatively impact on the development of veterinary medicines, since they tend to be more expensive and would thus be unable to ‘compete’ against human medicines. This would have a negative impact on the animal pharmaceuticals sector [industry];

- The usage of the cascade by definition increases risk as products are being used in ways in which they were not authorised. This is particularly true of the usage of human medicines within animals, which can be fatal [regulator];

- For certain products – particularly antimicrobials – usage of medicines in ways in which they were not intended would be very dangerous, particularly for human medicines [regulator].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.
Summary of impact assessment results:

- This option divided opinion. End user groups were largely in favour, mainly because extending the scope of the cascade would increase the range of medicines that veterinarians could use to treat animals. Specifically, end user groups argued that a relaxation of the cascade is needed for companion animals, since the risk to human health is lower. This need was seen to be particularly acute for minor species, where there are very few authorised medicines available. Proposed measures included allowing the cascade to be used for reasons other than a lack of availability of medicines (e.g. the use of human medicines because they tend to be cheaper), and permitting the importation and usage of medicines from third countries.

- Representatives from industry and regulatory bodies, however, were largely against this policy option. Industry consultees and survey respondents suggested that relaxing the cascade would effectively permit veterinarians to bypass the authorisation system, and would act as a strong disincentive for the development of new medicines and the extension of existing authorisations to new species and markets.

- Representatives from regulatory bodies stressed the potential risk to human and animal health of a relaxation of the cascade, even if this were restricted to companion animals (for example when they come into contact with humans). There was particular concern about the usage of human medicines within animals, in part for animal welfare reasons (e.g. due to problems calculating dosages), but also due to fears that this would encourage the unchecked usage of critical human antimicrobials.

A12.14 Option 14: Amending data protection to reward new product development

As shown in Table 3.17 on page 42, this policy option consists of 10 sub-options, the impacts of which are reviewed below.

A12.14.1 Sub-option 14.1: The maximum period of data protection is extended to 16 years

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.75:

- Survey respondents from industry awarded a minor positive score in terms of the impact on the availability of medicines, and a positive score in terms of the protection of human and animal health;

- Regulators were largely neutral about the impact of this policy option (many did not feel able to answer).
Figure A12.75 Survey respondents’ scoring of the policy option ‘the maximum period of data protection is extended to 16 years’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

-2.0
-1.0
0.0
1.0
2.0
Free movement
Admin burdens
Health protection
Availability

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- There is a risk that this policy option would harm the development of generic medicines, thus increasing the prices paid by end users [regulator and industry];
- Longer data protection periods encourage investment in R&D and the development of new medicines, particularly in small markets [industry];
- This policy option would not encourage investment in existing products with MAs over 16 years old (for instance the addition of a new species to a well-established product) [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- The suitability of the 16 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development. Views within the industry, predictably, differed between producers of generics and those developing novel products.
- Developers of novel products were supportive of the option, noting that the extension of the data protection period would increase the return on investment that could be achieved, and would thus make more marginal markets (e.g. minor species) more attractive (although the option as currently stated does not focus extended data protection periods on specific areas of need, e.g. minor species).
- Conversely, representatives of developers of generics products expressed concern that an extension of the data protection period would delay the entrance of generics products onto the market and affect the viability of the sector. Consultees noted that developers of novel products would receive 16 years of data protection even within profitable markets.
- The treatment of extensions to MAs under this policy option would need to be determined.
A12.14.2 Sub-option 14.2: The maximum period of data protection is extended to 20 years

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.76:

- Survey respondents from industry awarded this policy option a high positive score in terms of its impact on the availability of medicines and, related to this, the impact on the protection of human and animal health;
- Regulators were largely neutral about the impact of this policy option (many did not feel able to answer).

Figure A12.76 Survey respondents’ scoring of the policy option ‘the maximum period of data protection is extended to 20 years’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- There is a risk that this policy option would harm the development of generic medicines, thus increasing the prices paid by end users [regulator and industry];
- Longer data protection periods encourage investment in R&D and the development of new medicines, particularly in small markets [industry];
- 20 years of data protection is too long, and will provide too much of an advantage to companies developing novel products [regulator];
- This policy option would not encourage investment in existing products with MAs over 20 years old (for instance the addition of a new species to a well-established product) [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.
Summary of impact assessment results:

- The suitability of the 20 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development.
- Unsurprisingly, stakeholders from developers of novel products were supportive of this policy option. They noted that the extension of the data protection period would increase the return on investment that could be achieved. It was claimed that more marginal markets (e.g. minor species) would be more attractive (though others have disputed whether capital would in practice be allocated to smaller markets).
- Conversely, representatives of developers of generics products expressed concern that an extension of the data protection period would delay the entrance of generics products onto the market and affect the viability of the sector.
- This policy option does not focus extended data protection periods on specific areas of need (e.g. minor species), and it was noted by consultees that developers of novel products would receive 20 years of data protection even within profitable markets.
- The treatment of extensions to MAs under this policy option would need to be determined.

A12.14.3 Sub-option 14.3: An extra 3 years of protection is added for each extension to a MA, up to a maximum of 20 years

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.77:

- All stakeholders believed that this policy option would have a positive impact on the availability of medicines;
- Survey respondents from industry and from end user groups noted that this policy option would have a positive impact on the protection of human and animal health.

Figure A12.77 Survey respondents’ scoring of the policy option ‘an extra 3 years of protection is added for each extension to a MA, up to a maximum of 20 years’

*Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’*

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Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:
There is a risk that this policy option would harm the development of generic medicines, thus increasing the prices paid by end users [regulator];

There is a danger that the status of MAs would become increasingly complex and difficult for competent authorities to keep track of, thus creating administrative burdens for regulators [regulator];

20 years of data protection is too long, and will provide too much of an advantage to companies developing novel products [regulator];

It would be necessary to stipulate that an extension should involve a new species, not a new indication [regulator];

It would be beneficial to stipulate a time limit for the introduction of extensions, in order to encourage businesses to introduce such changes early in a product’s ‘life’ and thus reduce delays [end user group].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

**Summary of impact assessment results:**

- This option could encourage the authorisation and marketing of individual products for more species, if it is carefully specified.
- Consultees from industry were generally supportive of this option, which would increase the data protection period for each species added to a MA from 1 to 3 years. It was, however, suggested that this change would probably make the addition of major species to a MA a more attractive proposition, but would have little impact on the return on investment generated by adding a minor species.
- Regulators and developers of generics products raised a concern that the definition of an ‘extension’ to an MA should be carefully considered, and should be restricted to major developments (such as a new species). This proposal is contained in a separate policy option (see Option 14.4). It was suggested that unless this caveat was introduced, developers of novel medicines might repeatedly introduce minor extensions in order to protect themselves from competition from generics products, with an associated negative impact on the range of medicines available and the prices paid by end users.
- The suitability of the 20 years maximum period of data protection is difficult to assess. In practice for some species / indications this will probably be too long, and in others too short to justify investment in product development.

**A12.14.4 Sub-option 14.4: An extra 3 years of protection is added for each ‘major’ extension, and an extra 1 year is added for each ‘minor’ extension, up to a maximum of 20 years**

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.78:

- Survey respondents from industry and regulatory bodies awarded a negative score for this policy option in terms of its impact on administrative burdens;
- Representatives from industry and from end user groups awarded a positive score in terms of the impact of this policy option on the availability of medicines and the protection of human and animal health.
Figure A12.78 Survey respondents’ scoring of the policy option ‘an extra 3 years of protection is added for each ‘major’ extension, and an extra 1 year is added for each ‘minor’ extension, up to a maximum of 20 years’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- The distinction between major and minor extensions is positive and would prevent companies from using extensions to protect themselves from generics competitors [industry];
- There is a risk that this policy option would harm the development of generic medicines, thus increasing the prices paid by end users [regulator];
- Differentiating between a ‘major’ and a ‘minor’ innovation would be difficult and could be contentious, thus creating an administrative burden [regulator];
- It is unclear who would be a member of the committee and how it would be resourced [industry];
- A committee would probably generate further delays in product authorisations [industry];
- 20 years of data protection is too long, and will provide too much of an advantage to companies developing novel products, particularly if innovations were actually a sequence of minor amendments rather than substantive additions to a MA [regulator].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- As for Option 14.3, consultees from developers of novel medicines were supportive of an extension of the data protection period for each species added to a MA from 1 to 3 years, indicating that this would increase the return on investment. Regulators and developers of generics products were also in favour of the introduction of a distinction between major and minor extensions, noting that this would prevent companies from using MA extensions to protect
themselves from competition from generics products.

- Many consultees were concerned about how the proposed committee would operate, how it would be funded, and what impact it would have on the time taken to assess MA applications.
- The suitability of the 20 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development.

A12.14.5 Sub-option 14.5: Rewards for new product developments are decoupled from the initial authorisation

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.79:

- All stakeholders awarded this policy option a positive score in terms of its impact on the availability of medicines;
- Overall, survey respondents from industry and end user groups scored this policy option positively in terms of its impact on the protection of human and animal health.

Figure A12.79: Survey respondents’ scoring of the policy option ‘rewards for new product developments are decoupled from the initial authorisation’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- There is a risk that this policy option would harm the development of generic medicines, thus increasing the prices paid by end users [regulator];
- This policy option would enable extended data protection periods to be applied to existing MAs, thus encouraging innovation within the current product range [industry];
- The business case for investing in new developments for MUMS uses would be substantially increased by this policy option, thus increasing the availability of medicines [industry];
Safeguards would need to be introduced to ensure that companies did not repeatedly introduce minor changes to an existing authorisation in order to stifle competition from generics. This would need to include a strict definition of what constituted a new product development [regulator];

This policy option would have the most significant impact of all the options relating to data protection, since the current 5 year limit on the introduction of extensions does not fit with the way in which companies innovate [industry];

The data protection period for each new product development should be set at 10 years for each new species added to a MA [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- For industry this was the most popular of the options relating to data protection. The current 5 year 'limit' on the introduction of extensions was considered not to fit with the reality of how products are tested on the market for a period of time before decisions are made as to whether to invest in extensions to new species. It was suggested that the removal of this limit would have a significant impact on the availability of medicines, a proposition that was not opposed by representatives of generics producers.
- As it stands, this policy option would also apply any product with a MA, and thus authorisations granted many years ago could be extended to new species, with data protection. Again, industry representatives suggested that this could be a significant incentive to invest in innovation.

A12.14.6 Sub-option 14.6: The data protection period for environmental risks is changed to match that for safety and efficacy data

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.80:

- Representatives from regulatory bodies scored this policy option positively in terms of its impact on administrative burdens, and also on the availability of medicines;
- Survey respondents from industry suggested that this policy option would have a negative impact on administrative burdens, and little or no impact on the availability of medicines or the protection of human and animal health.
Figure A12.80  
Survey respondents’ scoring of the policy option ‘the data protection period for environmental risks is changed to match that for safety and efficacy data’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

▪ This policy option would remove an inconsistency within the legislation [industry, regulator and end user group];

▪ The beneficiaries of this policy option would be generics producers, for whom the cost of obtaining a MA would decrease. There might be a marginal increase in the number of generics products, and thus increased competition and lower prices [industry];

▪ In isolation this policy option would have a negative impact on producers of novel products, decreasing the return on investment for new products [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

▪ Consultees and survey respondents were largely in favour of this policy option, noting that the current treatment of environmental risk information is inconsistent when compared with other data. This policy option would correct this inconsistency and reduce the costs of obtaining an authorisation for a generic product, thus potentially increasing the number of such products on the market.

▪ Representatives from companies involved in the development of novel products claimed that this option would have a negative impact on the return on investment generated from new product development (since they currently benefit from unlimited data protection, thus increasing the cost of submitting an application for a generic product) and consequently did not want it to be implemented in isolation.
A12.14.7 Sub-option 14.7: The period of data protection for fish, bees and other specific species/indications is extended to 16 years

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.81:

- There was a consensus amongst all stakeholder groups that this policy option would have a minor positive impact on the availability of medicines, and by extension the protection of human and animal health.

Figure A12.81 Survey respondents' scoring of the policy option ‘the period of data protection for fish, bees and other specific species/indications is extended to 16 years’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

- There was a consensus amongst all stakeholder groups that this policy option would have a minor positive impact on the availability of medicines, and by extension the protection of human and animal health.

Figure A12.81 Survey respondents’ scoring of the policy option ‘the period of data protection for fish, bees and other specific species/indications is extended to 16 years’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Given that these species already have additional data protection, and that there are still problems with availability, it is questionable whether this proposal would have a significant impact on the availability of medicines [regulator];
- ‘Other specific species/indications’ would need to be carefully defined, and could include minor species such as goats, where extended data protection might encourage the extension of the MA of existing medicines into ‘similar’ minor species [industry];
- There are other problems with medicines for fish and bees that will not be solved by extended data protection. The bee industry is generally disinclined to use medicines where possible. The number of molecules suitable for use with fish is small, and substantial environmental safety packages are needed for such medicines [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- Representatives from developers of novel products were supportive of any extension to the data protection period, noting that this would increase the return on investment, and thus make these
areas more attractive. Producers of generic products, conversely, raised concerns that extensions to the data protection period prevent the entry of generics into the market, thus decreasing competition.

- The suitability of the 16 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development.
- Several stakeholders noted that fish and bees already benefit from extended data protection, and yet there remain problems with the availability of medicines, and thus that this policy option would in all likelihood not affect them. These markets are fundamentally small, and thus struggle to attract investment.
- It was suggested, however, that this option could have an impact depending on the definition of ‘other specific species/indications’. The development of new medicines to serve certain minor species is simpler (e.g. where they are similar to major species – e.g. cattle and goats), and an extension to the data protection period in such cases could make a significant difference.

A12.14.8 Sub-option 14.8: The period of data protection for fish, bees and other specific species/indications is extended to 20 years

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.82:

- Overall, regulators were neutral about this policy option in all impact areas, awarding a minor positive score in terms of the impact on the availability of medicines;
- Representatives from industry and end user organisations awarded a significant positive score in terms of the impact of this policy option on the availability of medicines and, by extension, the protection of human and animal health.

Figure A12.82 Survey respondents’ scoring of the policy option ‘the period of data protection for fish, bees and other specific species/indications is extended to 20 years’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:
Given that these species already benefit from additional data protection, and that there are still problems with availability, it is questionable whether this proposal would have a significant impact on the availability of medicines [regulator];

- 20 years of data protection is too long, and will provide too much of an advantage to companies developing novel products [industry];

- A 20 year data protection period, as opposed to 16 years, would increase the return on investment for new product development, but there are other problems with medicines for fish and bees that will not be solved by extended data protection. The bee industry is generally disinclined to use medicines where possible. The number of molecules suitable for use with fish is small, and substantial environmental safety packages are needed for such medicines [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- Representatives from developers of novel products were supportive of any extension to the data protection period, noting that this would increase the return on investment, and thus make these areas more attractive. Producers of generic products, conversely, raised concerns that extensions to the data protection period prevent the entry of generics into the market, thus decreasing competition.

- The suitability of the 20 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development.

- As with Option 14.7 the impact of this sub-option was doubted by several stakeholders who noted that fish and bees already benefit from extended data protection, and yet there remain problems with the availability of medicines. As with Option 14.7, this option could have an impact depending on the definition of ‘other specific species/indications’ in encouraging extension from major species (e.g. cattle and goats) to related minor species.

A12.14.9 Sub-option 14.9: MA extensions for small markets are rewarded with an extra 2 years of protection, up to 16 years

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.83:

- Representatives from industry awarded a minor positive score with regard to the impact of this policy option on the availability of medicines, and thus the protection of human and animal health;

- Survey respondents from regulatory bodies also scored this option positively in terms of its impact on the availability of medicines.
Figure A12.83: Survey respondents’ scoring of the policy option ‘MA extensions for small markets are rewarded with an extra 2 years of protection, up to 16 years’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

▪ The definition of ‘small market’ needs to be established before the impact of this policy option can be assessed [regulator, industry and end user group];

▪ Longer data protection periods encourage investment in R&D and the development of new medicines, so this policy option could make smaller markets (e.g. minor species) more attractive [industry];

▪ An extra 2 years of data protection will not be sufficient to warrant the investment in extending an existing MA to include a small market (presumably a minor species) [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

▪ This policy option needs to be better defined before the impact can be assessed, specifically what ‘small markets’ will include.

▪ The consensus amongst consultees and survey respondents from industry, where they felt able to comment, was that this policy option would have less of an impact than most of the other proposals for changing data protection. Two additional years of data protection was not considered sufficiently attractive to justify investing in extending a MA to a small market;

▪ The suitability of the 16 years maximum period of data protection is difficult to assess. In practice for some species/indications this will probably be too long, and in others too short to justify investment in product development.
Sub-option 14.10: MA extensions for small markets are rewarded with an extra 2 years of protection, up to 20 years

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.84:

- Representatives from industry awarded a minor positive score with regard to the impact of this policy option on the availability of medicines, and thus the protection of human and animal health;
- Survey respondents from regulatory bodies also scored this option positively in terms of its impact on the availability of medicines.

Figure A12.84 Survey respondents’ scoring of the policy option ‘MA extensions for small markets are rewarded with an extra 2 years of protection, up to 20 years’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- The definition of ‘small market’ needs to be established before the impact of this policy option can be assessed [regulator, industry and end user group];
- 20 years of data protection is too long, and will provide too much of an advantage to companies developing novel products [industry];
- Longer data protection periods encourage investment in R&D and the development of new medicines, so this policy option could make smaller markets (e.g. minor species) more attractive [industry];
- An extra 2 years of data protection will not be sufficient to warrant the investment in extending an existing MA to include a small market (presumably a minor species) [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.
Summary of impact assessment results:

- This policy option needs to be better defined before the impact can be assessed, specifically what ‘small markets’ will include.
- As with Option 14.9, consultees and survey respondents from industry who commented suggested that this policy option would have less of an impact than most of the other proposals for changing data protection. Two additional years of data protection was not considered sufficiently attractive to justify investing in extending a MA to a small market.
- As with the other cases, the suitability of the 20 years maximum period of data protection is difficult to assess.

A12.15 Option 15: Introducing support for SMEs

As shown in Table 3.18 on page 43, this policy option consists of 1 sub-option, the impacts of which are reviewed below.

A12.15.1 Sub-option 15.1: Introducing support for SMEs

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.85:

- Overall, regulators scored this option negatively in terms of its impact on administrative burdens;
- All stakeholders felt that this policy option would have a positive impact on the availability of medicines, and thus on the protection of human and animal health.

Figure A12.85 Survey respondents’ scoring of the policy option ‘introducing support for SMEs’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:
• There is limited evidence that assisting SMEs has any influence on whether companies choose to seek a MA. Free scientific advice might increase the success rate of MA applications, but will not increase the number of applications submitted [regulator];

• There should not be any market distortions introduced into the animal pharmaceutical industry, and the authorities should not favour one market segment over another [industry];

• Thought will need to be given the definition of a SME – in the animal pharmaceutical industry a SME might be the animal health division of a large human pharmaceutical company [industry];

• In some countries, regulators would not be permitted to operate a cost structure where the fees charged to one set of businesses (large companies) cross-subsidised the fees charged to another set of businesses (SMEs) [regulator].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

• Consultees reported that this option might have a slight impact on the availability of medicines, primarily by increasing the success rate of SMEs when applying for new MAs. There are issues for national competent authorities in implementing this option, since they will need to generate resources from elsewhere to fill the gaps resulting from reduced income from SMEs. In some countries cross-subsidisation of one group of businesses through higher charges to another is not allowed. A tight public spending environment puts pressure on use of finance raised from taxpayers.

A12.16 Option 16: Clarifying the scope of the legislation with regard to new treatments

As shown in Table 3.19 on page 43, this policy option consists of 1 sub-option, the impacts of which are reviewed below.

A12.16.1 Sub-option 16.1: Clarifying the scope of the legislation with regard to new treatment types

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.86:

• All three stakeholder groups scored this policy option positively in terms of its impact on the protection of human and animal health and the availability of medicines;

• Survey respondents from industry awarded a strong positive score in relation to the impact on the free movement of goods;

• Stakeholders all noted a slight negative impact on administrative burdens.
Figure A12.86 Survey respondents’ scoring of the policy option ‘clarifying the scope of the legislation with regard to new types of treatment’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- There are currently variations in approach between Member States, so harmonisation in this area would remove a barrier to the free movement of goods [regulator];
- A legislative approach might hinder innovation, and so the definitions adopted need to be flexible, and guidelines might be more appropriate [industry];
- It is important that a global approach is adopted in order to ensure harmonisation with other key markets (e.g. the United States) [industry];
- There is a risk that this option would lead to a growth in administrative burdens if, for instance, there was a resulting increase in the amount of data that companies were required to submit for an authorisation. The development of new medicines is important and should not be hampered by increased administrative burdens [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- There was widespread support for this policy option, which it was felt would introduce harmonisation where there is presently divergence between national approaches. This would have a positive impact on the operation of the single market.
- Stakeholders noted that legislating effectively within fast-changing and high technology areas is difficult, and that the legislation should be flexible enough to ensure that the definitions used do not hinder innovation. Furthermore, harmonisation with other major markets is as important as harmonisation within the EU/EEA.
A12.17 Option 17: Addressing the problem of antimicrobial resistance

As shown in Table 3.20 on page 44, this policy option consists of 5 sub-options, the impacts of which are reviewed below.

A12.17.1 Sub-option 17.1: Critical antimicrobials for human use are prohibited for use in the veterinary sector

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.87:

- Regulators and representatives from end user groups scored this policy option neutrally in respect of all impacts except for the effect on the availability of medicines, where a significant negative impact was expected;
- Survey respondents from industry also scored this option negatively in terms of its impact on the availability of medicines, and related to this also awarded a negative score in terms of the impact on the protection of human and animal health.

Figure A12.87 Survey respondents’ scoring of the policy option ‘critical antimicrobials for human use are prohibited for use in the veterinary sector’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Whilst this policy option might have a positive impact on the protection of human health (though the scientific link is currently unproven, and there is no empirical evidence that banning antimicrobials for use with animals affects resistance development), there would be major animal welfare implications where veterinarians were unable to treat animals and would be forced to resort to euthanasia [end user group];
- Restricting the usage of antimicrobials in animals would leave veterinarians reliant on a very small range of products. Thus in turn would make the responsible use of antimicrobials (e.g. by rotating or resting products) virtually impossible, thus potentially increasing the development of resistance [end user group];
The process of assembling a list of critical antimicrobials for humans would be difficult, and if left to the human medicines sector there is a danger that this list would include almost all antimicrobials [regulator];

The prohibition of antimicrobials within the animal health sector would significantly impair the development of new veterinary medicinal products. It is inconceivable that an entirely new range of animal-specific antimicrobials could ever be developed [industry];

There is little merit in banning antimicrobials for use in companion animals, though there may be a case for doing so in food-producing species [industry];

The restriction of critical antimicrobials through the cascade would perhaps be more workable and would have a greater impact [regulator];

In many countries and for many minor species (particularly turkeys and ducks), there is a lack of availability of antimicrobials. Consequently the option to make use of antimicrobials through the cascade is of critical importance [end user group];

This system already exists to some extent in some countries (e.g. Finland) [end user group];

This policy option would lead to increased illegal usage of human antimicrobials, which would have a serious negative impact on health protection [regulator].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- There was very little support for this policy option amongst consultees and survey respondents. Representatives from end user groups in particular were strongly against any restriction in the range of products that veterinarians can use to treat animals. There were claims that the banning of a significant group of antimicrobial products would have serious consequences for animal health. Some respondents suggested that if the law were followed, veterinarians would have to resort to euthanasia, and illegal and unchecked usage of critical human antimicrobials would increase.

- Many consultees challenged the science underpinning the assumption that banning the usage of critical human antimicrobial medicines within animals would have an impact on the development of antimicrobial resistance.

- Some countries already restrict the usage of critical antimicrobials without enforcing a universal ban.

A12.17.2 Sub-option 17.2: Potential impacts on antimicrobial resistance are addressed as part of the MA process

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.88:

- Overall, regulators and consultees from end user groups scored this policy option positively in terms of its impact on the protection of human and animal health, though consultees from industry awarded a negative score;

- All stakeholder groups scored this policy option negatively in terms of its impact on the availability of medicines, particularly those from industry and from end user groups.
Survey respondents’ scoring of the policy option ‘potential impacts on antimicrobial resistance are addressed as part of the MA process’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- This policy option already exists to some extent, and thus the scale of the impact would be limited [industry and regulator];
- There is a danger that the assessment would be the opinion of the evaluators rather than based on scientific judgement [industry];
- It will be important to ensure that data are also required for applications for generics products, since resistance changes over time and the situation may be different from when the application for the reference product was submitted [regulator];
- The risks associated with antimicrobial resistance if the product is used under the cascade should also be considered [regulator].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- Antimicrobial resistance is already included in the assessment process (see Section 3.2.18), and so the additional impact of this policy option would be limited. There was, however, a consensus amongst regulators and end users that this policy option would have a positive impact on the protection of health, provided the requirements also applied to generics, and the assessment of resistance included consideration of usage under the cascade.
A12.17.3 Sub-option 17.3: Veterinarians are prohibited from selling antimicrobials

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.89:

- Regulators awarded a positive score in respect of the protection of human and animal health, and a slightly negative score in terms of the impact on the availability of medicines;
- Representatives from industry scored this policy option negatively in almost all areas, particularly the impact on the availability of medicines and the protection of human and animal health.

Figure A12.89 Survey respondents’ scoring of the policy option ‘veterinarians are prohibited from selling antimicrobials’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- This option would have a significant negative impact on veterinary practices, for whom the income from selling medicines is often critical to their viability. In practice this policy option would lead to closures of marginal veterinary practices, which tend to be located in rural areas. The impacts on human and animal health of the fragmentation of the network of veterinarians (which is critical in the early identification of epidemics) would be more serious than the benefits gained from restricting the usage of antimicrobials [end user group];
- In some countries (e.g. Poland), only veterinarians may sell animal medicines, and thus this policy option would require changes to supply chain legislation to enable pharmacists to sell antimicrobials [regulator];
- This proposal would be unworkable in rural areas where owners/farmers would have to travel considerable distances to a pharmacist. Moreover, rural pharmacists would be unlikely to stock sufficient quantities of antimicrobials due to variations in demand [end user group];
▪ Veterinarians would still need to be able to distribute small quantities of antimicrobials to meet immediate needs (e.g. emergency use, or usage during the weekend) [regulator];

▪ There is a danger that this restriction would stimulate the black market trade in antimicrobials [industry];

▪ This option would require the SPCs and packaging/labelling for all existing antimicrobial products to be amended, creating a considerable administrative burden [regulator].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

▪ There was little support for this policy option amongst consultees and survey respondents. Representatives from end user groups suggested that restrictions on the operations of veterinary practices would have a serious impact on their viability, and would lead to practice closures.

▪ Consultees from end user groups questioned whether this policy option would have any effect on tackling antimicrobial resistance, claiming that there was no empirical evidence available that veterinarians are over-prescribing antimicrobials simply to generate additional income.

▪ Consultees and survey respondents suggested that it would have a significant negative impact on animal health, since situations would arise – particularly in rural areas – where veterinarians needed to be able to distribute antimicrobials immediately, but could not. They claimed there is a danger that this would stimulate the illegal trade and usage of antimicrobials which, since it would be unregulated and unmonitored by veterinarians, would pose risks to human and animal health.

▪ This policy option would generate a cost to industry. SPCs and product packaging and labelling would need to be revised for all authorised antimicrobials in order to reflect the changes to their method of distribution.

A12.17.4 Sub-option 17.4: A system is established for collecting data on the sales and usage of antimicrobials

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.90:

▪ All three stakeholder groups scored this policy option positively in terms of its impact on the protection of human and animal health;

▪ This option was associated with a slightly negative impact on administrative burdens, particularly amongst representatives from industry.
Survey respondents’ scoring of the policy option ‘a system is established for collecting data on the sales and usage of antimicrobials’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- In some countries (e.g. the UK) a system of collecting and reporting data on the prescription and usage of antimicrobials already exists [regulator];
- Efforts will need to be made to ensure that this system is fully automated and harmonised across all countries, otherwise there is a danger that this policy option will create a significant administrative burden for industry [industry];
- Data on the usage of antimicrobials is much harder to collect and more likely to contain errors [regulator];
- Data on usage will need to be combined with data on resistance if it is to have any impact, otherwise this option simply imposes an administrative burden [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- Elements of this policy option already exist to varying degrees, (particularly for food-producing species), and so the basis for such a system is in place to build upon. Stakeholders were almost unanimously in favour of this proposal, provided it is implemented effectively and does not create an excessive administrative burden on businesses and veterinarians.
A12.17.5 Sub-option 17.5: Controls on the advertising and marketing of antimicrobials to veterinarians

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.91:

- Regulators and end user groups awarded a small positive score in terms of the impact of this policy option on the protection of human and animal health, but survey respondents from industry believed that this option would have a negative impact on health protection;
- Representatives from industry awarded a negative score in terms of the impact on administrative burdens, and also suggested that this option would have a negative impact on the availability of medicines.

Figure A12.91 Survey respondents’ scoring of the policy option ‘controls on the advertising and marketing of antimicrobials to veterinarians’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Enforcing this requirement would be difficult for the authorities [regulator];
- Advertising and marketing are important mechanisms through which MA holders keep veterinarians informed about the latest developments, and removing this source of information would negatively impact on veterinarians’ abilities to make available the most suitable medicines [industry];
- If information on antimicrobial products was not provided by the animal health industry, veterinarians would simply resort to other sources, which might lead to misinterpretation of the correct use of products [industry];
- Veterinarians are professionals and are qualified to assess the claims made by companies [end user group];
- The advertising of information on the withdrawal periods of antimicrobials can put pressure on veterinarians, since farmers wish to have the shortest possible withdrawal period, even though this might not be the most suitable product [end user group];
A code of practice for advertising and marketing to veterinarians would be more suitable than an outright ban [industry];

It is more important to ensure that antimicrobials are not marketed directly to end users (e.g. farmers), as is still the case in a small number of countries [end user group].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

Consultees and survey respondents expressed concerns about the workability of this proposal, particularly the enforcement by the authorities. Representatives from both end user groups and industry argued that advertising and marketing is a crucial means of communicating information on product developments, and ensures that veterinarians are fully informed about the correct usage of antimicrobials. There was little support for an outright ban on advertising and marketing, though it was suggested that other approaches – e.g. restrictions on the information that can be promoted (e.g. withdrawal periods) and/or a code of practice – might be beneficial.

Representatives from all stakeholder groups suggested that the advertising and marketing of antimicrobials to end users (farmers and companion animal owners) was more problematic since this led to pressure being applied to veterinarians. In most countries the advertising and marketing of antimicrobials to ‘laypersons’ is banned or restricted, but interpretations of laypersons vary between countries, and there may be a need for further harmonisation or control measures.

A12.17.6 Option 18: Improving harmonisation and oversight of in-market control

As shown in Table 3.21 on page 44, this policy option consists of 2 sub-options, the impacts of which are reviewed below.

A12.17.7 Sub-option 18.1: National control systems are required to meet agreed European standards, and the Commission has the powers to check such systems

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.92:

- Stakeholders scored this option neutrally in terms of the impact that it would have on the free movement of goods, the availability of medicines, and administrative burdens;
- All stakeholders awarded this policy option a strong positive score in terms of its impact on the protection of human and animal health.
Figure A12.92: Survey respondents’ scoring of the policy option ‘national control systems are required to meet agreed European standards, and the Commission has the powers to check such systems’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

- Further details on the nature of the control system standards that would be required are needed before the impact of this policy option can be assessed [industry, regulators and end user groups];
- Harmonisation of control systems between countries would ensure a level playing field and would improve the operation of the single market [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- Consultees were in principle supportive of greater harmonisation of control systems, noting that this would have a positive impact on the operation of the single market and on the protection of human and animal health. However, most requested further detail on the content of the control system standards, and did not feel able to draw conclusions on this policy option until such information was made available.

A12.17.8 Sub-option 18.2: Harmonised EU sanctions are introduced for non-compliance

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.93:

- Survey respondents awarded a neutral score for this policy option in respect of its impacts on the availability of medicines (except for end user groups), the free movement of goods and administrative burdens;
- It was noted by stakeholders that this policy option would have a positive impact on the protection of human and animal health.
Figure A12.93: Survey respondents’ scoring of the policy option ‘harmonised EU sanctions are introduced for non-compliance’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Base = 12 responses (industry); 14 responses (regulators); 5 responses (end users)

Comments received from consultees and survey respondents as regards this policy option were as follows:

▪ There are already sufficient sanctions in place, so this policy option would have a limited impact [industry];
▪ The harmonisation of sanctions across the EU/EEA would ensure a level playing field [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

▪ Consultees were in principle supportive of the harmonisation of sanctions across the EU/EEA, noting that this would have a positive impact on the operation of the single market and on the protection of human and animal health. However, it was noted that sanctions already exist across the EU/EEA, and thus that this policy option would not have a significant impact on non-compliance.

A12.18 Option 19: Enforcing a European database of authorised products

As shown in Table 3.22 on page 45, this policy option consists of 1 sub-option, the impacts of which are reviewed below.

A12.18.1 Sub-option 19.1: Enforcing a European database of authorised products

The scores awarded by survey respondents as regards the impacts of this policy option are summarised in Figure A12.94:

▪ All stakeholders awarded minor positive impact scores to this policy option in respect of its effect on the free movement of goods, the availability of medicines and the protection of human and animal health;
Survey respondents also noted that this policy option would be associated with a slight negative impact on administrative burdens.

Figure A12.94 Survey respondents’ scoring of the policy option ‘enforcing a European database of authorised products’

Average score awarded by survey respondents based on a scale where -2 means ‘significant negative impact’ and +2 means ‘significant positive impact’

Comments received from consultees and survey respondents as regards this policy option were as follows:

- There is a danger that the information contained in the database would quickly become out-of-date, thus limiting its usefulness [industry];
- A set of harmonised data reporting protocols are needed in order to facilitate data entry [industry];
- This option would place a considerable administrative burden on the competent authorities, who are already under pressure to reduce costs [regulator];
- Awareness of what is on the market would help industry to focus its R&D investments [industry].

This policy option would not have an impact on the administrative burdens imposed on industry, and thus it is not necessary to develop a SCM for this option.

Summary of impact assessment results:

- A database of authorised products was supported by most consultees and survey respondents, who noted that it would provide a valuable resource that could be used by industry, regulators and veterinarians alike. The major benefit of the database would be to improve transparency within the authorisation system. Veterinarians would be able to see which products were available where, information that could be valuable if medicines were unavailable (with implications for the operation of the cascade). It was also suggested that the database would highlight inconsistencies between countries, for instance variations in SPCs for the same product.
- To work effectively though the database would need to be underpinned by harmonised reporting protocols, to ensure that the information submitted by the competent authorities was consistent.
The database would also need to be regularly updated if it was not to become a historical record of authorisations. Ensuring that stakeholders were aware of how often the database was updated would ensure confidence in the data contained within.