In response to information provided by the competent authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.
Executive Summary

This fact-finding mission on the prudent use of antimicrobials in animals took place in Spain from 20 to 28 October 2016 and is part of DG Health and Food Safety’s planned series of such missions to Member States. The objectives of this fact-finding mission were to gather further information on the practical implementation of measures aimed at tackling issues concerning antimicrobial resistance (AMR) relating to the use of veterinary medicines and to identify examples of good practice which could be helpful to other Member States in addressing this issue.

Spain was the highest user of veterinary antimicrobials in 2014 of the countries providing data to the European Surveillance of Veterinary Antimicrobial Consumption project and, according to the Spanish Agency for Medicines and Medical Devices, sales have increased further during 2015. Spain is also one of the highest users of antimicrobials in human medicine.

A national AMR strategy for the period 2014 to 2018, based on a One Health approach, has been developed with six strategic aims and associated actions in human and veterinary areas. These are mainly qualitative in nature and rely on voluntary initiatives given the lack of a legal basis for obliging prudent use principles to be followed in Spain. The main focus of work carried out to date is on enhancing the monitoring and surveillance of the use of antibiotics, understanding the health status of farms (especially starting with biosecurity in the pig sector) and in raising awareness of AMR issues among officials, veterinarians and the farming sector.

Overall, the report concludes that, whilst it is too early to see how effective the AMR action plan will be, there are indications that significant reductions in the use of antimicrobials in Spain can be achieved without adversely affecting productivity and costs. These indications stem from a voluntary national initiative to reduce the use of colistin and from the individual efforts of farmers, veterinarians and producer groups.
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Annex 1 Legal References
ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

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| AEMPS        | Spanish Agency for Medicines and Medical Devices  
              Agencia Española de Medicamentos y Productos Sanitarios |
| AMR          | Antimicrobial resistance |
| CIAs         | Critically important antimicrobials |
| ECDC         | European Centre for Disease Prevention and Control |
| ESBL         | Extended-spectrum β-lactamase producing organisms |
| ESVAC        | European Surveillance of Veterinary Antimicrobial Consumption |
| ESVAC-ES     | Spanish project for surveillance of veterinary antimicrobial consumption |
| EU           | European Union |
| MAPAMA       | Ministry of Agriculture, Fisheries, Food and Environment  
              Ministerio de Agricultura, Pesca, Alimentación y Medio Ambiente |
| MRSA         | Methicillin-resistant Staphylococcus aureus |
| OECD         | Organisation for Economic Co-operation and Development |
| PCU          | Population correction unit |
| PRAN         | Strategic action plan to reduce the risk of selection and dissemination of antibiotic resistance  
              Plan Nacional de Resistencia a los Antibióticos |
1 INTRODUCTION

This fact-finding mission, carried out in agreement with the Spanish competent authorities, took place from 20 to 28 October 2016 and was the eighth in a planned series of missions to nine Member States during 2016. The mission team, comprising of two auditors from DG Health and Food Safety, a national expert from a Member State and an observer from the European Centre for Disease Prevention and Control (ECDC), was accompanied throughout the mission by representatives of the competent authority, the Spanish Agency for Medicines and Medical Devices (AEMPS) 1. On 20 October 2016, an opening meeting was held with representatives from the AEMPS, the Ministry of Agriculture, Fisheries, Food and Environment (MAPAMA) 2 and the autonomous communities of Castilla-Leon and Catalonia, where the objectives, scope and itinerary for the fact-finding mission were confirmed.

2 OBJECTIVES AND SCOPE

The objectives of this fact-finding mission were to (a) gather further information on the practical implementation of measures aimed at tackling the issues concerning antimicrobial resistance (AMR) relating to the use of veterinary medicines and (b) identify examples of good practice which could be helpful to other Member States in addressing this issue.

In terms of scope, the mission team examined the regulatory framework on veterinary medicines and on medicated feed currently in place in Spain (including for companion animals) and the implementation of existing recommendations and guidelines on the prudent use of antimicrobials in veterinary medicine – including those published by the Commission referred to in section 3. The following topics were not included in the scope of this mission: (i) the monitoring and reporting of AMR in zoonotic and commensal bacteria in certain food-producing animal populations and in food and (ii) the monitoring of residues and contaminants in live animals and animal products. These two topics were the subject of audits in September 2016 (DG(SANTE)/2016-8678) and in January 2013 (DG(SANCO)/2013-6760), respectively.

In pursuit of these objectives, the following meetings and visits took place:

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1 The AEMPS is a State Agency of the Ministry of Health, Social Services and Equality, whose responsibilities include, amongst others, the evaluation and authorisation of medicines for human and veterinary use: [https://www.aemps.gob.es/en/lAEMPS/presentacion/home.htm](https://www.aemps.gob.es/en/lAEMPS/presentacion/home.htm)

2 At the time of the mission, this was known as the Ministry of Agriculture, Food and Environment.
3 MISSION RATIONALE

This fact-finding mission forms part of one of the initiatives included in the European Commission's action plan against the rising threats from AMR, and is specifically linked to actions 2 and 3 of the associated road map: namely to strengthen the regulatory framework on veterinary medicines and on medicated feed and to introduce recommendations for prudent use in veterinary medicine, including follow-up reports. Separate actions are foreseen under the road map concerning the prudent use of antimicrobials in human medicine.

In preparing its guidelines for the prudent use of antimicrobials in veterinary medicines (Commission Notice: 2015/C299/04 of 11 September 2015), the Commission received information highlighting a number of measures already taken by Member States on this topic. In order to gain a more comprehensive overview of the efforts being made within the EU to encourage the prudent use of antimicrobials in veterinary medicine, a questionnaire was sent by DG Health and Food Safety to all Member States in September 2015 and nine Member States were selected to be involved in this series of fact-finding missions in 2016. The main points from these fact-finding missions and the questionnaire responses will be presented in an interim overview report intended to highlight good practices and particular challenges identified in applying the prudent use of antimicrobials in veterinary medicine.

4 FINDINGS

4.1 NATIONAL STRATEGIES AND ACTION PLANS INFLUENCING THE USE OF ANTIMICROBIALS IN ANIMALS

1. A 5-year national strategic action plan (Plan Nacional de Resistencia a los Antibióticos 2014-2018 – PRAN) based on a One Health approach was adopted on 5 March 2014 and subsequently approved in plenary meetings of the Inter-territorial Council of the National Health System and MAPAMA. The PRAN is developed around two broad objectives, namely to reduce the risk of selection and dissemination of AMR, and to preserve the existing therapeutic arsenal of antibiotics in a sustainable manner.

2. The PRAN sets out the case for taking action based on the increasing prevalence of AMR in those bacteria causing infections in hospitals and communities and data indicating that antibiotics are often used inappropriately in both human and animal health care. In this respect, it cites reports published by ECDC and the Organisation for Economic Co-operation and Development (OECD) which show that Spain is among the highest users of antimicrobials in patients admitted to hospitals throughout the EU. While the use of antimicrobials for patients in primary care in Spain (which accounts for 90% of antibiotic consumption) was comparable to that in other Member States,

prescriptions for certain critically important antimicrobials (CIAs) (cephalosporins and quinolones) exceeded those for all other OECD countries. The PRAN notes that excessive and frequent inappropriate use of antibiotics amounts to approximately 50% of antibiotic use in primary and hospital care. For animals, the main area of concern highlighted in the PRAN is the predominant use of antimicrobials in oral forms for mass / herd treatments which are often given for preventive reasons. This is borne out by the 2014 European Surveillance of Antimicrobial Consumption (ESVAC) report 7 (see point 7) and is supported by the findings of this mission (see Section 4.2).

3. A dedicated team within the AEMPS is responsible for the overall management and coordination of the development and implementation of the PRAN while there are two coordination committees (health care professionals and autonomous communities), numerous ministries, organisations and experts in 20 working groups (6 ministries, all autonomous communities, 61 organisations and 240 experts) which are responsible for the elaboration of specific measures and actions for each of the 6 strategic areas included in the PRAN. The 6 areas for action apply equally to human and animal health and include: (a) surveillance of antibiotic consumption and AMR; (b) control of AMR (c) identification of alternative and / or complementary measures of prevention and treatment; (d) defining research priorities; (e) training and information for healthcare professionals and; (f) communication and awareness raising in the population as a whole and in specific sub-groups. So far, the priorities and actions have been defined for each of the six strategic areas in the PRAN and work is on-going to implement them. For 2016-2017, 6 priority actions relating to animal health and 7 for human health have been highlighted. Progress made is summarised in yearly reports and various newsletters published by the AEMPS.

4. The PRAN is largely qualitative in nature and is expected to lead to reductions in the use of antibiotics through changing attitudes. The AEMPS emphasised that the PRAN can be amended at any time and consideration is being given to introducing quantitative targets for reducing antibiotic use although these may be largely voluntary (such as the on-going initiative to reduce consumption of colistin in animals – see point 28) given the limited legal basis for setting mandatory targets.

5. The PRAN emphasises the tremendous intrinsic complexity of decisions regarding the use of antimicrobials, the sparse microbiological information and insufficient knowledge of infectious diseases as key factors which lead to an inappropriate choice or duration of treatment with antibiotics. It also notes that a common system for electronic prescriptions in human and veterinary medicine would allow greater control of antibiotic use, leading to a reduction in the levels of AMR.

6. Arrangements for funding the various actions under the PRAN are currently being finalised. According to the AEMPS, the Ministry of Health and MAPAMA have already set aside funding for this purpose.

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4.2 MONITORING OF SALES OF ANTIMICROBIALS AND LEVELS OF AMR

4.2.1 Monitoring of sales of antimicrobials

7. According to the most recent ESVAC report for 2014, sales of antimicrobials, including CIAs, have risen by 25% since 2011 and their use in Spain is now the highest reported by those countries contributing data to the project (418.8 mg/population correction unit – PCU –, being 3.1 and 391.5 mg/PCU the lowest and second highest use reported, respectively). According to the AEMPS, the apparent upward trend in sales of antimicrobials during the last few years can be partly explained by previous under-reporting. Nevertheless, preliminary data indicates that sales of antimicrobials for use in animals have continued to rise by approximately 10% in 2015, and there is little sign of a downward trend in 2016, with the exception of colistin, which is the subject of a national voluntary programme (see point 28).

8. In 2014, sales of antimicrobials for food producing animals amounted to nearly 3 000 tonnes of active ingredient of which 0.8% were 3rd and 4th generation cephalosporins (0.33 mg/PCU, while the average sales for 25 countries in that year was 0.26 mg/PCU) and 2.4% were fluoroquinolones (9.92 mg/PCU, while the average sales for 25 countries in that year was 2.99 mg/PCU). Sales of these CIAs were relatively stable in the last few years. According to the AEMPS, sales of colistin in 2014 were equivalent to 36 mg/PCU mainly in medicated premixes.

9. Several actions to improve the accuracy and level of detail in the monitoring of antibiotic usage are set out under the first strategic objective of the PRAN. Sales data is currently provided by the industry on a voluntary basis except for distributors which are legally obliged to do so. A specific on-line system called ESVAC–ES ⁸ has been developed for collecting sales data in a harmonised form from wholesalers and retailers.

10. Initiatives are underway, as part of the PRAN, to collect data on the sales of antimicrobials by species. It is intended that the data collected will facilitate controls on the use of CIAs, provide the basis for educating prescribers and help to identify problems and potential good and bad practices which can be included in training and other awareness raising activities. For 2016, the ESVAC-ES system includes the means to collect declarations of the estimated sales by species based on the species indicated in the summary of product characteristics. Where there are several species listed, the declarations will be approximations.

11. A more elaborate approach is being taken to obtain accurate data concerning the use of antimicrobials by species. The AEMPS and MAPAMA have drafted national legislation to provide a legal basis for collecting data on prescriptions and are developing a central database at national level to store the data. The General Council of Veterinary Colleges has developed a model system of electronic prescriptions which can be used throughout Spain which will enable data to be fed to the central database. The AEMPS has

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developed three apps CIMAVET (Centro de Información online de Medicamentos Veterinarios), CIMAVET APP and NOMENCLATOR VETERINARIO. The first two of these provide an on-line source of up-to-date information regarding veterinary medicinal products, which can also be accessed via mobile devices. The third app provides information on all veterinary medicinal products authorised in Spain and automatically inputs information from various sources into the electronic prescription system and ultimately to the central database. This includes a facility to automatically upload information to third party systems such as those operated by integrated producers which manage their own prescriptions.

12. PRESCRIVET, the electronic prescription system developed by the General Council of Veterinary Colleges includes digital signatures and validation codes which authenticate the prescribers of veterinary medicinal products. Farmers are assigned a unique code and the public administration has access to the system. Through this, the system aims to provide safe storage of the data and ensure traceability and proper recording by all operators. Farmers registered in the system can see all the information entered by the prescriber and any prescriptions which have not been dispensed. The information recorded includes the diagnosis, number and group (e.g. pen / shed etc.) of animals to be treated. It provides for off-label uses to be recorded and also includes a category ‘not valid for dispensing’ which enables veterinarians to prescribe treatments using antibiotics obtained previously by the animal owner. The €200 000 cost of developing the system was borne by the General Council of Veterinary Colleges, pharmacies can join via a hub run by the Pharmacy College, while other users require an ‘e-signature’. These are administered by a private company and cost €12 / year, except for veterinarians who are not charged. All veterinarians must be registered with one of the Veterinary Colleges to practice and they can access PRESCRIVET. PRESCRIVET is one of many electronic prescription platforms being developed, with both autonomous communities visited during the mission establishing their own systems. The various electronic prescription systems described to the mission team largely replicate the approach taken by the PRESCRIVET system.

13. The use of electronic prescription systems is currently voluntary and, according to the General Council of Veterinary Colleges, covers approximately 5-10% of all prescriptions. The uptake of these systems is expected to increase, with interest from pig farmers and other sectors. A number of issues influencing the speed at which the electronic prescription systems are likely to be used have been identified. These include the need to learn how to use the system and making its use routine but also to ensure the accuracy of data entered into the system and those veterinarians and others using the system can feel secure and confident about all of their prescribing activities being recorded in official databases. Currently, only veterinarians can access the data entered into PRESCRIVET and discussions are on-going to make the use of electronic prescriptions mandatory and to enable the competent authorities to have access to the information in the database.

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14. As part of the pilot project for ESVAC-ES, a 3 month programme to obtain information on the use of antibiotics in the pig sector was carried out from June to August, 2015. In one of the autonomous communities visited, 22 pig farms (considered to be representative of the production within the area) were chosen to be involved in the programme. The data gathered (in cooperation with the farmers and their veterinarians), included the production stage of the animals treated, the trade name and form of the products used and the main conditions they were intended to treat. A sample of the data provided to the mission team indicated that in several cases, colistin, amoxicillin and oxytetracycline were administered in medicated feed as preventive treatments for diarrhoea, meningitis or respiratory conditions. In several other cases, doxycycline, tylosine and colistin were administered in medicated feed for reasons given as ‘initiation of fattening’.

4.2.2 Monitoring of AMR

15. The PRAN highlights increasing levels of AMR in bacteria responsible for infections in hospitals, notably in *Escherichia coli* where resistance to cephalosporins in extended spectrum beta-lactamase (ESBL) *E. coli* has been detected. In addition, information published by the AEMPS in October 2016, shows that one in three *E. coli* infections of the urinary tract being is resistant to quinolones (one of the most commonly used antimicrobials to treat such cases) and notes that *E. coli* strains resistant to carbapenems and colistin have also been detected in Spain. More concerning is the increase in carbapenamase-producing *Enterobacteriaceae*. In 2008, more than 30% of bacterial strains causing infections in hospitals were multi-drug resistant and in the case of *Acinetobacter baumanii* the results of the most recent study cited in the PRAN indicated that 94% of strains were multi-drug resistant, 86% were extremely drug resistant and 2% of the strains were resistant to all available antibiotics (pandrug-resistant). Problems with human strains of methicillin-resistant *Staphylococcus aureus* (MRSA) overshadow those caused by MRSA in livestock, for which monitoring is limited to pigs. Indeed, according to the 2015 EU report 10 on antimicrobial resistance, the only Member States which provided information on monitoring programmes (excluding clinical investigations) were Belgium (bovine) and Germany and Spain (porcine).

16. Improving the surveillance of AMR is one of the strategic action areas identified in the PRAN and, for animals, the priority actions have focussed on establishing and implementing a nationwide project for monitoring pathogenic bacteria in accordance with EU requirements. This topic was the subject of an audit by DG Health and Food Safety carried out in September 2016 (see section 2).

17. Publications of the European Food Safety Authority highlight that the levels of resistance to fluoroquinolones in strains of *Salmonella* collected from broilers, turkeys and laying hens (based on samples collected in accordance with EU requirements) and in fattening pigs and poultry meat were above the EU average \(^{11}\). A similar situation was found regarding fluoroquinolones and macrolides (erythromycin) in strains of *Campylobacter jejuni* \(^{12}\) collected from broilers, turkeys and calves.

4.3 DISTRIBUTION MODEL FOR VETERINARY ANTIMICROBIALS IN SPAIN

4.3.1 Authorisation and distribution

18. The prescription, distribution and use of veterinary medicinal products are regulated by national legislation (Royal Decree 109/1995). This specifies, among others, that all veterinary antimicrobial products are available only on a prescription issued by a veterinarian and they can only be dispensed by authorised pharmacies, farmer groups or associations and authorised commercial distributors. Veterinarians may dispense sufficient veterinary medicinal products to initiate treatments.

19. Although these national rules prevent veterinarians from directly profiting from the sales of veterinary medicinal products, they may still do so indirectly (e.g. through their employment with farmers’ groups of producers of medicated feed) where part of their salaries may depend on achieving sales targets. The AEMPS acknowledged that in such cases, veterinarians could have a clear conflict of interest between financial / employment concerns on the one hand while on the other hand being required to prescribe veterinary antimicrobials prudently. In one case, the link between veterinarians' salaries and sales of veterinary antimicrobials had been used to encourage reductions in their use by making payment of the 20% variable portion of the salaries partly dependent on meeting targets for reduced sales of veterinary medicinal products. It was acknowledged however, that the effectiveness of this measure could be limited if farmers were to obtain prescriptions from other veterinarians.

20. Veterinarians met during the mission noted that the lack of any requirements for a committed, close working relationship with animal keepers (e.g. a one-to-one contract between a veterinarian and farmer) leaves them vulnerable to pressure to prescribe antimicrobials when this is not necessarily appropriate, as the animal keeper can simply look elsewhere to find a veterinarian willing to meet their demands.

21. According to the General Sub-Directorate of Resources in Animal Production of MAPAMA, the central competent authority responsible for animal feed (including medicated feed), approximately 14% of the 31 million tonnes of compound feed produced in Spain annually contains veterinary medicinal products, including antimicrobials. In total there are 553 commercial feed business operators and 172

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producing for their own use approved to produce medicated feed in accordance with EU requirements. These operators may obtain medicated premixes on the basis of an order form signed by a veterinarian and subsequently use them to produce feed when prescribed by a veterinarian. The veterinarians and competent authorities met during the mission confirmed that there are clear indications that antimicrobials are routinely administered in medicated feed for preventive or metaphylactic treatments. Three large operators visited during the mission confirmed this. One of the operators noted that piglets at weaning are systematically treated with amoxicillin in medicated feed and, prior to this, colistin was included in all three types of feed given to piglets during the weaning stage.

22. The requirements governing the production of medicated feed are incorporated into national legislation. The methodology and criteria to be applied when measuring homogeneity and carry over (of medicines into non-medicated feed) were discussed and approved by the national feed committee for animal nutrition, prior to publication in 2014. These establish the acceptable values for homogeneity and carry over. In the latter case, levels of carry-over below 1% are considered acceptable. For carry-over of active ingredients detected at levels between 1 to 3%, operators must show measures are in place as would be required for coccidiostats by EU legislation. As such, carry-over of antimicrobials (active ingredient) into non-medicated feed at levels up to 3% would be acceptable, if it were intended for species for which the antimicrobial is authorised and if the species concerned were not especially sensitive to the medication. According to a major producer of medicated feed met, the upper limit could be achieved without taking any measures to minimise carry-over even further. The results of official controls on this topic indicate that levels of carry-over above 1% are rarely detected in the official controls programmes carried out in most years (see point 46).

23. National legislation does not allow the distance-selling of veterinary medicinal products for which a veterinary prescription is required.

24. Where there are no authorised veterinary medicinal products for a disease, national legislation provides that the veterinarian may (at his own risk and, in particular, to avoid causing unacceptable suffering) treat the animals affected in accordance with the cascade provided for in EU legislation. There are no other national restrictions on the off-label use of veterinary medicinal products in Spain.

25. It is obligatory for farmers to record any unused or returned medicines and for veterinary clinics to have a system for returning unused medicines.

4.3.2 Special conditions for authorisation of antimicrobials

26. The AEMPS advised that the product information has been updated as required for all veterinary antimicrobial products concerned by the referral outcomes specified in Commission Decision C(2010)4684 of 1 July 2010 for veterinary medicinal products for food producing animals containing quinolones and/or fluoroquinolones as active substances and those in Commission Implementing Decision C(2012)182 of 13 January 2012 for veterinary medicinal products which contain the active substances cefquinome and ceftiofur.

27. Control of the use of CIAs and specific surveillance of their use is included in one of the strategic lines of the PRAN. CIAs have been defined as those which are indispensable for the treatment of infections caused by multi-resistant bacteria in humans and those considered as a priority are colistin, fluoroquinolones and 3rd and 4th generation cephalosporins.

28. In 2016, a 3-year voluntary plan was initiated under the PRAN in order to reduce the use of colistin (from its current level of 36 mg/PCU down to 5 mg/PCU) as specified in the updated advice on the use of colistin products in animals published by the European Medicines Agency on 27 July 2016. The programme is initially aimed at pigs as this sector accounts for the highest consumption of colistin. Two working groups have been established with the aim of understanding the use of antibiotics (including colistin) on farms, to set annual reduction targets and deadlines. The AEMPS estimates that the companies participating in the programme currently represent 35% of Spanish pig production, although it anticipates that ongoing awareness raising activities, combined with political influence, will encourage most of the sector to join the programme within the next year.

29. Several large operators met during the mission reported that they had until recently administered colistin in medicated feed to piglets at all stages of weaning. In one case, the use of colistin has been halved during 2016 and although mortality had increased temporarily on 10-20% of farms, the situation had been rectified with little use of alternative antibiotics. In another case, colistin was used consistently in feed for piglets since 2013 although it was gradually being phased out with a target of ceasing its use by the end of 2016. The operator noted that although the formulation of the first feed given at weaning was changed to make it more digestible, the overall consumption of feed had actually increased as the levels of antibiotics within it were reduced, which had enhanced productivity and profitability. It was noted that the operator was still using certain antimicrobials (e.g. amoxicillin) and zinc oxide routinely in certain formulas. The substantial reductions in colistin use which have been achieved with few negative and some positive effects, suggests much of the colistin use in the pig sector is either excessive or unnecessary.

4.4 Policies / Practices encouraging reduction in use and prudent use of antimicrobials in animals and outcomes to date

30. Efforts to encourage the prudent use of antimicrobials in animals are encompassed by two of the six strategic lines of the PRAN which are based on interventions to optimise the use of antibiotics and the identification and spearheading of alternative and or complementary measures of prevention and treatment. Areas of action under these strategic lines can be summarised as reducing the need for antibiotics and ensuring their responsible and prudent use. Within these areas, priority is being given to information gathering, raising awareness of good practice (including in animal hygiene, handling and wellbeing) and encouraging the development and use of susceptibility tests and rapid diagnostic methods to inform decisions regarding the need for, and choice of, antibiotics for use in animals.

31. In recent years, the two autonomous communities visited have carried out an extensive survey of pig farms as part of a national initiative to assess the level of biosecurity measures in place based those set down in national legal requirements adopted in 2000. In total, over 10 000 on-the-spot assessments have been carried out by officials and veterinarians working for sub-contracted companies, utilising a standard checklist with sections covering: (a) the structure and conditions of the farms, (b) the quarantine system for incoming animals, (c) the hygiene routines (cleaning / disinfection) and (d) registration systems (e.g. records for use of veterinary medicinal products, and movement records for live and dead animals). The critical points within each section are weighted to provide comparable data for the farms. This initiative has been implemented previously for poultry farms through the performance of biosecurity surveys which form part of the Salmonella control programmes.

32. The detailed official analysis of the results from these biosecurity assessments is ongoing but, in one of the autonomous communities, nearly 80% of the 4 000 farms visited were considered to have high or very high biosecurity standards based on the national requirements. Only 3% of farms were considered to have low biosecurity standards. There was some variation in the results due to the level of biosecurity measures which could be applied in extensive versus intensive production systems. Overall, it is too early to identify any factors which could help to explain the relatively high use of antimicrobials in the Spanish pig sector. Once the assessments are complete, it is envisaged that the results will be used as the basis for classifying farms in terms of their health status, which will help to determine factors such as the frequency of official controls to which they will be subjected.

33. Separately to these assessments, the large integrated company visited has established a programme of annual on-site audits by its team of veterinarians to evaluate the performance of their producers in a range of topics, including biosecurity, good hygiene practice, welfare and use of veterinary medicinal products. The results are sent to producers highlighting areas for improvement but they are also being used for comparative purposes and to map internal and external risks. The company noted that
these efforts are likely to enhance customers’ perception of their products and help them meet customer requirements regarding the use of veterinary medicinal products.

34. The AEMPS has sought to recognise achievements in reducing the use of veterinary antimicrobial products through award schemes. A PRAN award will be granted for the best initiatives in (a) monitoring and control of consumption of antibiotics and AMR, (b) research on AMR, (c) scientific publications on AMR (d) training and information to health professionals on AMR and (e) communication and public awareness about AMR.

35. In one of the autonomous communities visited, a voluntary health plan for the pig sector is currently being drafted in collaboration with the competent authorities and representatives of the industry which is expected to be operational in 2017. It will go further than required in national legislation to provide an organised programme to improve herd health through the adoption of plans for disease management and the use of veterinary medicinal products. Only those producers which were categorised at a high level in the biosecurity survey described above and have satisfactory systems to record the use of veterinary antimicrobials will be eligible to participate in the scheme when it is launched. Members of the scheme will need to fulfil various criteria including having: (a) a contract with a trained veterinarian for provision of health care based on a minimum frequency of farm visits, (b) an action plan for the rational use of antimicrobials and (c) must avoid the prophylactic use of veterinary antimicrobials. Furthermore, the use of CIAs must be justified by the results of susceptibility tests and information about the use of antimicrobials must be available. A trained veterinarian would supervise the scheme.

36. Efforts to raise awareness about the responsible and prudent use of antimicrobials in animals have focussed on producing guidance and increasing accessibility to information on-line (see point 11) and through training sessions. The mission team was provided with numerous examples of guidance which have been prepared by the competent authorities, organisations and operators which mostly cover the information given in the Commission’s prudent use guidelines (see Section 3) and incorporate elements of guidance published by other organisations such as the Federation of European Companion Animal Veterinary Associations. The multi-disciplinary forum known as Vet+i, which covers nearly 300 bodies (42 public and 57 veterinary organisations, 21 other associations, 109 research centres and 109 companies within the animal health and research sectors), has produced a range of species specific guidelines which encompass the general principles of good practice in the responsible and prudent use of antimicrobials. Further guidelines have also been published by organisations and companies, some of which include examples of good hygiene practice and information relating to the use of veterinary antimicrobials. Veterinarians treating small animals met noted that it would be useful to have a leaflet or other information available to inform pet owners as to the reasons why antimicrobials are not routinely prescribed.

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16 www.vetmasi.es
37. The AEMPS is currently preparing a guide, to be made available on-line, which will collate the guidance already available and also classify the veterinary antimicrobials available into the most appropriate first, second and third choice of antimicrobials to treat a range of common conditions in farmed animals, taking into account the local epidemiological situation. This guidance will be prepared with the assistance of expert working groups.

38. The AEMPS, the competent authorities in the autonomous communities and large companies met had carried out a range of training activities to highlight the principles of prudent use of antimicrobials based on the guidance available. In several cases, these had also highlighted alternative strategies (such as vaccinations or feed additives) and the role of factors such as genetics of breeding stock, the importance of feed quality and good hygiene practice. These efforts had helped to ensure that the veterinarians and operators met during the mission were generally familiar with the principles for the prudent use of veterinary antimicrobials.

39. The AEMPS has established a platform which will consider issues affecting the quality, reliability and development of susceptibility tests. Opportunities to utilise those intended for human health will also be considered. The mission team saw numerous examples of susceptibility tests carried out by veterinarians and producers and although the results were generally taken into account when selecting the most appropriate antibiotic to use, this was not always the case. Reasons given for not considering the results of these tests included differences between the activity of antimicrobials in-vivo and in-vitro and, in particular for CIAs, the price, withdrawal period or treatment regime were more important factors. The small animal veterinarian visited highlighted the financial implications of carrying out susceptibility tests routinely as pet owners were reluctant to pay the €65 cost of each test.

40. The potential benefits of a closer and more robust focus on biosecurity, hygiene and management practices in reducing the use of antimicrobials was highlighted by the farmers visited. Largely on their own initiative and working closely with their veterinarians, the farmers met had achieved an approximate 50% cut in their use of antimicrobials by making changes in these areas. Critical factors identified by the farmers included the health status of animals brought onto the farm, mostly by reducing to a minimum the number of suppliers and selecting genetically robust stock, the implementation of vaccination programmes, ensuring effective disinfection between batches and putting in place disease monitoring and surveillance programmes.

41. Most of the farmers met noted that additional time and effort and some financial investments had been needed to make the necessary management changes and to improve structural aspects such as the ventilation in animal houses. The switch from routine preventive treatments in medicated feed to administering treatments when symptoms appear had required investment to upgrade the drinking water system to enable its use for oral administration of antimicrobials when necessary. Although these changes required some investment or a temporary increase in costs, these were mainly offset by increased productivity. In some cases, the reductions or changes in the use of
antimicrobials provided a market advantage and enabled producers to participate in schemes such as those requiring no antimicrobials to be administered during the final 100 days of production.

4.5 CONTROL ACTIONS ON THE USE OF ANTIMICROBIALS IN ANIMALS

42. The official control of the distribution and use of veterinary antimicrobial products is under the responsibility of MAPAMA, the competent authorities for feed (at central level and their respective services in the autonomous communities – the Consejería de Agricultura y Ganadería in Castilla-Leon and the Departament d’Agricultura, Ramaderia, Pesca I Alimentació and the Agència de Salut Pública in Catalonia). A full description of the organisation and distribution of responsibilities for controls of veterinary medicinal products and medicated feed is given in the country profile for Spain 17.

43. Official controls to check compliance with the EU and national legal requirements governing the distribution, prescription and use of veterinary medicinal products are elaborated centrally into two national programmes, which are implemented by the relevant competent authorities in the autonomous communities. One programme covers controls for the distribution, prescription and dispensing of veterinary medicinal products, while the other covers the control of hygiene at primary production level. Compliance with the EU and national requirements for the production of feed, including medicated feed, is covered by the national control programme for feed.

44. In both autonomous communities visited, regular risk-based controls were carried out at an established minimum frequency throughout the chain from distribution to use of veterinary medicinal products (in Catalonia all wholesalers, 20% of authorised distributors, 20% of private veterinarians and 3% of farms are to be inspected each year). It is however, problematic to identify prescribing veterinarians visiting farms (as there is no register) and the so-called mobile veterinarians who are not based at a practice.

45. The results of these control programmes showed a high level of compliance with the legal requirements in wholesalers and distributors of veterinary medicinal products. Veterinary teams were inspected for the first time in 2013 in one of the autonomous communities and non-compliances were detected in all 15 inspections carried out in 2014 and in 87% of those performed in 2015. These ranged from relatively minor administrative issues to excessive quantities of veterinary medicinal products found left-over on farms or being used without prescriptions. In 2015, 33 non-compliances were identified in more than 1 000 on-farm inspections, mainly concerning registration and records of veterinary medicinal products, hygiene and other cleanliness issues. Fines were imposed in eight cases.

17 http://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=ES
All producers of medicated feed were planned to be controlled in 2015, although priority was given to those placing feed on the market or producing relatively high volumes of feed. In 5 out of 219 controls, feed was found to contain authorised veterinary medicinal products other than those prescribed. Authorised veterinary medicinal products were detected in 16 out of 316 checks of non-medicated feed, mostly due to carry-over. According to the central competent authorities, these include cases where the level of carry-over was above the limit of detection and do not necessarily indicate that the levels of 1% or 3% of carry-over of active ingredient permitted in national legislation (see point 22) were exceeded.

5 OVERALL CONCLUSIONS

Spain was the highest user of veterinary antimicrobials in 2014 of the countries providing data to the European Surveillance of Veterinary Antimicrobial Consumption project and, according to the Spanish Agency for Medicines and Medical Devices, sales have increased further during 2015. Spain is also one of the highest users of antimicrobials in human medicine.

A national AMR strategy for the period 2014 to 2018, based on a One Health approach, has been developed with six strategic aims and associated actions in human and veterinary areas. These are mainly qualitative in nature and rely on voluntary initiatives given the lack of a legal basis for obliging prudent use principles to be followed in Spain. The main focus of work carried out to date is on enhancing the monitoring and surveillance of the use of antibiotics, understanding the health status of farms (especially starting with biosecurity in the pig sector) and in raising awareness of AMR issues among officials, veterinarians and the farming sector.

The report concludes that, whilst it is too early to see how effective the AMR action plan will be, there are indications that significant reductions in the use of antimicrobials in Spain can be achieved without adversely affecting productivity and costs. These indications stem from a voluntary national initiative to reduce the use of colistin and from the individual efforts of farmers, veterinarians and producer groups.

6 CLOSING MEETING

A closing meeting was held on 28 October 2016 with the representatives of the competent authorities. At this meeting, main findings and preliminary conclusions of the mission were presented by the mission team. The competent authorities did not indicate any disagreement with these.
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