

## **Report on the European Commission's Public Online Consultation:**

***Better regulation of veterinary pharmaceuticals: how to put in place a simpler legal framework, safeguarding public and animal health while increasing the competitiveness of companies.***

### **1. INTRODUCTION**

The European Commission is preparing a legal proposal on the review of the legal framework for veterinary medicinal products.

On 13 April 2010 a public consultation was launched on the key issues of the forthcoming legal proposal. The consultation document 'Better regulation of veterinary pharmaceuticals: how to put in place a simpler legal framework, safeguarding public and animal health while increasing the competitiveness of companies' was published on the Commission website and was available through the 'Commission's IPM tool (Interactive Policy Making) from 13 April until 15 July 2010. The consultation document is presented in Annex 1.

Annex 2 contains a full list of the names of all responding organisations or citizens. The individual responses of those respondents who did not make a specific request for confidentiality will be published on the Pharmaceuticals website.

### **2. BREAKDOWN OF RESPONSES**

We received 172 responses to the web-based consultation via the Interactive Policy Making Tool. We received four additional responses to the consultation by letter or email outside the Interactive Policy Making Tool. The comments in these additional responses are included in this report. However, they have not been integrated in the tables setting out a quantitative analysis of the results. Table 2.1 gives a breakdown of the responses by type of respondent.

<b>2.1 Category of participants</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (172)</b>
Citizen	26	15,12%	15,12%
Non-business organisation	28	16,28%	16,28%
Business organisation / enterprise	89	51,74%	51,74%
A public authority	29	16,86%	16,86%
<b>In case of business organisation or enterprise, type of stakeholder</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (172)</b>
Farmer	7	7,87%	4,07%
Veterinarian	40	44,94%	23,26%

Manufacturer	4	4,49%	2,33%
Wholesaler	1	1,12%	0,58%
Pharmaceutical industry	35	39,33%	20,35%
Importer	0	0,00%	0,00%
Researcher	1	1,12%	0,58%
Other	4	4,49%	2,33%

### 3. RESPONSES TO KEY ISSUES

The statistics of the public consultation are included in this report. The percentages are calculated on both the total number of replies to the consultation and total replies to the specific question.

### 4. KEY ISSUES:

#### 4.1. Data exclusivity

Stakeholders' views differ as to the appropriateness of the level of data protection provided by the current legal framework (see table 4.1.1). Overall, the responses can be divided into two categories. One large group (70 respondents; about 41 %) considers that the level of data protection is satisfactory without substantiating their position any further. This group is made up mostly of veterinarians and farmers. Another group considers that the level of data protection is unsatisfactory (47 respondents; 27 %) or very unsatisfactory (8 respondents; about 5%). This category is made up entirely of pharmaceutical companies .

<b>4.1.1 Please indicate your satisfaction with the level of data protection provided by the current legal framework</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (138)</b>
No opinion	12	6.98 %	8.70 %
Very unsatisfactory	8	4.65 %	5.80 %
Unsatisfactory	47	27.33 %	34.06 %
Satisfactory	70	40.70 %	50.72 %
Very satisfactory	1	0.58 %	0.72 %
N/A	-	19.77 %	-

<b>4.1.2 Do you have quantitative or qualitative data showing the impact of the current data exclusivity period on innovation (yes, no)? If so please provide estimate of impact?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (130)</b>
Yes	27	15.70 %	20.77 %
No	103	59.88 %	79.23 %
N/A	-	24.42 %	-

Limited data was provided on the effective data protection period for the first application of a new veterinary medicinal product.

<b>4.1.3 Do you have data on effective protection periods of originator products calculated from the authorisation of the originator until the first authorisation of a generic?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (172)</b>
Yes	13	7.56 %	7.56 %
No	159	92.44 %	92.44 %

Only six respondents disagree with the statement that generic companies are conducive to a competitive market (see table 4.1.4). Most respondents (124; 72 %) agreed with this statement.

<b>4.1.4 Do you agree that generic companies provide for a competitive market within the veterinary pharmaceutical industry that is reflected in the pricing structure of veterinary medicines which is passed on to the end user?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (138)</b>
No opinion	8	4.65 %	5.80 %
Strongly disagree	6	3.49 %	4.35 %
Agree	116	67.44 %	84.06 %
Strongly agree	8	4.65 %	5.80 %
N/A	-	19.77 %	-

A total of fifty respondents considered the current data exclusivity period to be unsatisfactory or very unsatisfactory; nineteen respondents indicated that the current situation was satisfactory or very satisfactory (see table 4.1.5). Almost all pharmaceutical companies developing new products consider the current data exclusivity period to be unsatisfactory.

<b>4.1.5 Do you consider that the current data exclusivity period in the legal framework strikes the appropriate balance between innovation and competition?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (136)</b>
No opinion	67	38.95 %	49.26 %
Very unsatisfactory	23	13.37 %	16.91 %
Unsatisfactory	27	15.70 %	19.85 %
Satisfactory	15	8.72 %	11.03 %
Very satisfactory	4	2.33 %	2.94 %
N/A	-	20.93 %	-

Most respondents (101; 69 %) agree that the general data protection period of 10 years should be increased (table 4.1.6). The vast majority (109; 63 %) consider that the current additional

data exclusivity period of one year for each extension of the original authorisation is inappropriate (see table 4.1.7) and would be in favour of major product developments having their own period of data protection (120; 71 %) (see table 4.1.8).

<b>4.1.6 Would you agree to increase the general period of data protection of 10 years?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (135)</b>
No opinion	12	6.98 %	8.89 %
Strongly disagree	22	12.79 %	16.30 %
Agree	69	40.12 %	51.11 %
Strongly agree	32	18.60 %	23.70 %
N/A	-	21.51 %	-

<b>4.1.7 Do you consider the current additional data exclusivity period of one year for each extension of the authorisation to another food-producing species appropriate?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (135)</b>
No opinion	10	5.81 %	7.41 %
Very unsatisfactory	27	15.70 %	20.00 %
Unsatisfactory	82	47.67 %	60.74 %
Satisfactory	14	8.14 %	10.37 %
Very satisfactory	2A	1.16 %	1.48 %
N/A	-	21.51 %	-

<b>4.1.8 Would you be in favour of major product developments (for example extending the authorisation to additional animal species, new formulations of the substance) being subject to their own period of exclusivity (i.e. not being part of the global marketing authorisation for the product containing that active substance)?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (135)</b>
Favour not at all	4	2.33 %	2.96 %
Favour not	5	2.91 %	3.70 %
Favour somewhat	70	40.70 %	51.85 %
Favour clearly	17	9.88 %	12.59 %
Favour very much	35	20.35 %	25.93 %
Do not know	4	2.33 %	2.96 %
N/A	-	21.51 %	-

Most respondents (63%) would be in favour of amending the condition whereby it is only in a five-year period following the granting of the initial marketing authorisation that an extension of the period of data exclusivity can be obtained (see table 4.1.9).

**4.1.9 Would you be in favour of amending the condition that only in a time period of five years following the granting of the initial marketing authorisation an extension of the period of market exclusivity can be obtained?**

	Number of replies to the question	% of total replies to the consultation (172)	% of replies to the question (135)
Favour not at all	4	2.33 %	2.96 %
Favour not	14	8.14 %	10.37 %
Favour somewhat	70	40.70 %	51.85 %
Favour clearly	8	4.65 %	5.93 %
Favour very much	30	17.44 %	22.22 %
Do not know	9	5.23 %	6.67 %
N/A	-	21.51 %	-

Many respondents refer to the negative effects which the global marketing authorisation concept has on innovations. This concept does not take into account the investment and innovation involved into further developing a product.

Most respondents consider that data protection rules place a particularly heavy burden on SMEs (see table 4.1.10). Further analysis shows that the majority of industry respondents do not consider that there is a specific burden on SMEs (Yes 3 %, No 53 %, Do not know 27 %, N/A 17 %). Veterinarians, however, hold the opposite opinion (Yes 75 %, No 2 %, Do not know 11 %, N/A 12 %).

**4.1.10 Do you consider that in data protection rules there are particular burdens in relation to the features of SMEs?**

	Number of replies to the question	% of total replies to the consultation (172)	% of replies to the question (132)
Yes	70	40.70 %	53.03 %
No	34	19.77 %	25.76 %
Do not know	28	16.28 %	21.21 %
N/A	-	23.26 %	-

Most respondents (65%) would like to introduce specific intellectual property incentives for small markets (see table 4.1.11). Only a very small majority (5%) would not be in favour.

**4.1.11 Should specific intellectual property incentives be developed for small markets?**

	Number of replies to the question	% of total replies to the consultation (172)	% of replies to the question (130)
Yes	111	64.53 %	85.38 %
No	8	4.65 %	6.15 %
Do not know	11	6.40 %	8.46 %
N/A	-	24.42 %	-

The respondents considered that the current exclusivity period of 13 years for fish and bees is insufficient (54 %) and should be extended (56 %) (see table 4.1.12).

<b>4.1.12 Do you consider the current data protection period of 13 years for fish and bees appropriate?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (134)</b>
Yes	17	9.88 %	12.69 %
No	93	54.07 %	69.40 %
Do not know	24	13.95 %	17.91 %
N/A	-	22.09 %	-

The public were asked to indicate which species should receive the same approach as bees and fish. Almost all those who provided comments considered that the same exclusivity period should apply for all minor species and minor uses.

<b>4.1.13 Should the data period of 13 years for bees and fish be extended to other species?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (134)</b>
No opinion	11	6.40 %	8.21 %
Very unsatisfactory	8	4.65 %	5.97 %
Unsatisfactory	5	2.91 %	3.73 %
Satisfactory	97	56.40 %	72.39 %
Very satisfactory	13	7.56 %	9.70 %
N/A	-	22.09 %	-

Most respondents considered that generics increase the availability of medicines (see table 4.1.14).

<b>4.1.14 Do you agree that generics increase the availability of veterinary medicines (e.g. in smaller Member States in which the original product was not marketed)?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (136)</b>
No opinion	8	4.65 %	5.88 %
Strongly disagree	34	19.77 %	25.00 %
Agree	35	20.35 %	25.74 %
Strongly agree	59	34.30 %	43.38 %
N/A	-	20.93 %	-

About half of the respondents (48 %) consider that generic veterinary products based on old reference products could pose a risk for public or animal health (see table 4.1.15).

**4.1.15 Generic veterinary products may be based on reference products that have been on the market for a long time, and the approval of these reference products will have taken place**

<b>not according to current requirements. Do you consider that generic veterinary products based on these 'old reference products could pose a risk for public or animal health?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (140)</b>
Yes	84	48.84 %	60.00 %
No	50	29.07 %	35.71 %
Do not know	6	3.49 %	4.29 %
N/A	-	18.60 %	-

Most respondents (100; 58 %) felt that an generic should be allowed to use environmental data (see table 4.1.16). Industry respondents pointed out that environmental safety data requirements could be adapted if a level playing field was guaranteed for all marketing authorisation holders.

<b>4.1.16 Do you think an applicant should be allowed to use the data in relation the potential risks posed by medicinal product for the environment (like for the results of safety and residue test or of the pre-clinical and clinical trials?)</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (128)</b>
Yes	100	58.14 %	78.13 %
No	14	8.14 %	10.94 %
Do not know	14	8.14 %	10.94 %
N/A	-	25.58 %	-

No clear position emerged on the establishment of a monograph system for environmental risks: 34% of the respondents had no opinion, 18% were not in favour, 10% somewhat in favour and 18 % clearly or very much in favour.

<b>4.1.17 Would you favour a monograph system for environmental risks?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (138)</b>
Favour not at all	25	14.53 %	18.12 %
Favour not	6	3.49 %	4.35 %
Favour somewhat	18	10.47 %	13.04 %
Favour clearly	14	8.14 %	10.14 %
Favour very much	17	9.88 %	12.32 %
Do not know	58	33.72 %	42.03 %
N/A	-	19.77 %	-

## 4.2. Authorisation procedure

About 74% of the respondents are dissatisfied or very dissatisfied with the current authorisation procedure and only a minority (23; 13%) appears to be satisfied. This last group of respondents consists mostly of authorities (11), veterinarians (4) and two business respondents active in homeopathics.

<b>4.2.1 How do you rank your satisfaction with the current authorisation procedures?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (136)</b>
No opinion	4	2,33%	2,94%
Very dissatisfied	4	2,33%	2,94%
Dissatisfied	105	61,05%	77,21%
Satisfied	23	13,37%	16,91%
Very satisfied	0	0,00%	0,00%
N/A	-	20,93%	-

A majority of respondents (100; 58%) considered that there is no need for several authorisation procedures in the EU (see table 4.2.2). However, a substantial minority (35; 20%) believed that there is a need for several procedures. This minority consisted of authorities (12), veterinarians (10) and almost all respondents active in aquaculture (3). Similar results were obtained on the question whether it is necessary that the number of authorisation procedures should be simplified by reducing it to one as 62% of the respondents agreed to this position (see table 4.2.3).

<b>4.2.2 Do you consider that there is a need for several authorisation procedures in the EU?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (138)</b>
Yes	35	20,35%	25,36%
No	100	58,14%	72,46%
Don't know	3	1,74%	2,17%
N/A	-	19,77%	-

<b>4.2.3 Do you consider it necessary that the number of authorisation procedures should be simplified by reducing it to only one?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (139)</b>
No opinion	4	2,33%	2,88%
Strongly disagree	27	15,70%	19,42%
Agree	76	44,19%	54,68%
Strongly agree	32	18,60%	23,02%
N/A	-	19,19%	-



A majority of the respondents (71; 41%) consider that there are parts in the authorisation procedures in particular burdensome for SMEs. The respondents that did not agree with this statement (29;17%) consisted mostly of industry (19) and authorities (5).

<b>4.2.4 Do you consider that there are parts in the authorisation procedures in particular burdensome for SMEs?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (124)</b>
Yes	71	41,28%	57,26%
No	29	16,86%	23,39%
Do not know	24	13,95%	19,35%
N/A	-	27,91%	-

About 59% of the respondents expressed to be satisfied or very satisfied with the current centralised procedure and about 12% of respondents appear to be dissatisfied or very dissatisfied (table 4.2.5). This last group of respondents consists of industry (8), veterinarians (5), authorities (3) and food producers (3).

<b>4.2.5 How do you rank your satisfaction with the current centralised procedure?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (133)</b>
No opinion	8	4,65%	6,02%
Very dissatisfied	3	1,74%	2,26%
Dissatisfied	20	11,63%	15,04%
Satisfied	96	55,81%	72,18%
Very satisfied	6	3,49%	4,51%
N/A	-	22,67%	-

There appears to be strong support among respondents (120; 72%) to extend the scope of the centralised procedure (see table 4.2.6).

<b>4.2.6 Would you favour extending the scope of the Community procedure (extending the type of products that could be authorised by the Community procedure)?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (136)</b>
Favour not at all	4	2,33%	2,94%
Favour not	8	4,65%	5,88%
Favour somewhat	15	8,72%	11,03%
Favour clearly	93	54,07%	68,38%
Favour very much	12	6,98%	8,82%

Do not know	4	2,33%	2,94%
N/A	-	20,93%	-

About 64% of the respondents are dissatisfied or very dissatisfied with the current mutual recognition and decentralised procedure (see table 4.2.7). A minority (18; 10 %) appeared to be satisfied. This last group of respondents consisted mostly of authorities (11).

<b>4.2.7 How do you rank your satisfaction with the current decentralised and mutual recognition procedure?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (135)</b>
No opinion	7	4,07%	5,19%
Very dissatisfied	5	2,91%	3,70%
Dissatisfied	105	61,05%	77,78%
Satisfied	18	10,47%	13,33%
Very satisfied	0	0,00%	0,00%
N/A	-	21,51%	-

The reputation for efficiency and scientific expertise of the competent authority appear the most important criteria for selecting it as reference member state, followed closely by previous favourable experience and reputation for communication (see table 4.2.8). The geographical location seems to be of less importance.

<b>4.2.8 What are your criteria for selecting the reference Member State in the decentralised procedure?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (172)</b>
Previous favourable experience	34	19,77%	19,77%
Reputation for efficiency	42	24,42%	24,42%
Reputation for scientific expertise	38	22,09%	22,09%
Reputation for communication	28	16,28%	16,28%
Geographical location	24	13,95%	13,95%
Other	12	6,98%	6,98%

There appears to be a strong support (68% of respondents) for a conditional authorisation system (see table 4.2.9).

<b>4.2.9 Do you think a conditional authorisation, similar to the one included in the legal framework for human medicines, would help to mitigate the availability problem?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (131)</b>
No opinion	9	5,23%	6,87%
Strongly disagree	4	2,33%	3,05%
Agree	113	65,70%	86,26%

Strongly agree	5	2,91%	3,82%
N/A	-	23,84%	-

Most respondents to the public consultation (51%) did not favour to include indirect risks in the risk-benefit assessment of veterinary medicines (table 4.2.10). However, a majority (58%) favoured to include in the legal framework a basis for restricting a marketing application in cases where authorisation of a specific medicine would pose an indirect risk to animal or human health (see table 4.2.11).

<b>4.2.10 Would you favour including in the legal framework a requirement to perform a risk-benefit assessment which also takes into account indirect risks related to the use of the veterinary medicine, for example the development of antimicrobial resistance?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (132)</b>
Favour not at all	26	15,12%	19,70%
Favour not	62	36,05%	46,97%
Favour somewhat	13	7,56%	9,85%
Favour clearly	15	8,72%	11,36%
Favour very much	12	6,98%	9,09%
Do not know	4	2,33%	3,03%
N/A	-	23,26%	-

<b>4.2.11 Would you favour including in the legal framework a clear basis for restricting a marketing application and/or providing certain indications in cases where authorisation of the specific veterinary medicine would pose an indirect risk to animal or human health?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (139)</b>
Favour not at all	23	13,37%	16,55%
Favour not	9	5,23%	6,47%
Favour somewhat	69	40,12%	49,64%
Favour clearly	18	10,47%	12,95%
Favour very much	13	7,56%	9,35%
Do not know	7	4,07%	5,04%
N/A	-	19,19%	-

A majority (51%) of respondents favoured not to include in the legal framework a specific legal basis to restrict the use of antimicrobials which are critical for human medicines (table 4.2.12).

<b>4.2.12 Would you favour that the legal framework provides a specific legal basis to restrict the use of antimicrobials which are critical for human medicine?</b>			
	<b>Number of replies to the</b>	<b>% of total replies to the consultation</b>	<b>% of replies to the question</b>

	question	(172)	(138)
Favour not at all	80	46,51%	57,97%
Favour not	7	4,07%	5,07%
Favour somewhat	22	12,79%	15,94%
Favour clearly	13	7,56%	9,42%
Favour very much	13	7,56%	9,42%
Do not know	3	1,74%	2,17%
N/A	-	19,77%	-

### 4.3. Packaging and labelling

Regarding packaging and labelling requirements for veterinary medicines the stakeholders were asked six questions. It can be extracted from their answers, firstly, that the majority of the stakeholders believe that it is clearly essential or very much essential to have packaging and labelling requirements at EU level (see table 4.3.1).

<b>4.3.1 Do you consider EU - packaging and labelling requirements essential in terms of providing appropriate information to the users of veterinary medicines?</b>			
	Number of replies to the question	% of total replies to the consultation (172)	% of replies to the question (142)
Not essential at all	1	(0.6%)	(0.7%)
Not essential	5	(2.9%)	(3.5%)
Somewhat essential	11	(6.4%)	(7.7%)
Clearly essential	104	(60.5%)	(73.2%)
Very much essential	20	(11.6%)	(14.1%)
Don't know	1	(0.6%)	(0.7%)
N/A	30	(17.4%)	-

When they were asked if they would be in favour of reducing the requirement and the information needed in the packages and labels (see tables 4.3.2 and 4.3.3) most of the participants were positive about the idea.

Concerning the possibility of having fewer or non packaging and labelling requirements at all (see table 4.3.2) half of the stakeholders, mostly consisting of veterinarians, are somewhat in favour. The authorities answered mostly negatively to this question. Respondents of industry were clearly or very much in favour.

<b>4.3.2 Would you be in favour of fewer packaging and labelling requirements, or none at all, in the EU legal framework?</b>			
	Number of replies to the question	% of total replies to the consultation (172)	% of replies to the question (140)
Favour not at all	14	(8.1%)	(10%)
Favour not	17	(9.9%)	(12.1%)

Favour somewhat	71	(41.3%)	(50.7%)
Favour clearly	9	(5.2%)	(6.4%)
Favour very much	29	(16.9%)	(20.7%)
Do not know	0	(0%)	(0%)
N/A	32	(18.6%)	-

With regard to the possibility of reducing the information on the label, most of the participants would be somewhat in favour of the measure (see table 4.3.3). They are basically veterinarians and the authorities. Stakeholders from the industry are mainly the ones clearly or very much in favour of this idea.

<b>4.3.3 Would you be in favour of reducing the information on the label as much as possible and to making it easier for labels to be used in a number of Member States?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (138)</b>
Favour not at all	5	(2.9%)	(3.6%)
Favour not	8	(4.7%)	(5.8%)
Favour somewhat	74	(43%)	(53.6%)
Favour clearly	9	(5.2%)	(6.5%)
Favour very much	42	(24.4%)	(30.4%)
Do not know	0	(0%)	(0%)
N/A	34	(19.8%)	-

On the issue about allowing Member States to decide which language is to be used for labelling and packaging (see table 4.3.4), the majority are positive.

<b>4.3.4 Would you favour Member States being allowed to decide which language is to be used for labelling and packaging?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (139)</b>
Favour not at all	2	(1.2%)	(1.4%)
Favour not	5	(2.9%)	(3.6%)
Favour somewhat	67	(39%)	(48.2%)
Favour clearly	43	(25%)	(30.9%)
Favour very much	21	(12.2%)	(15.1%)
Do not know	1	(0.6%)	(0.7%)
N/A	33	(19.2%)	-

Regarding the possibility of having specific requirements for small packs (see table 4.3.5) most the stakeholders agree or strongly agree with it.

<b>4.3.5 Can you agree to have specific requirements for small packs (small packaging would include ampoules, blister packs and other immediate packs of relative small size), e.g. information being given on the outer packaging of small packs?</b>
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	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (137)</b>
No opinion	2	(1.2%)	(1.5%)
Strongly disagree	1	(0.6%)	(0.7%)
Agree	92	(53.5%)	(67.2%)
Strongly agree	42	(24.4%)	(30.7%)
N/A	35	(20.3%)	-

About half of the respondents (79 out of the 172 participants in the public consultation) gave concrete proposals to amend the legal framework. Two main groups of proposals could be established.

#### **4.4. Pharmacovigilance and monitoring**

The majority of respondents agree or strongly agree that the needs and expectations concerning the safety level of veterinary pharmacovigilance should be different from those concerning human medical products (see table 4.4.1). Most of those respondents are veterinarians and representatives from the industry.

<b>4.4.1 Do you consider that the needs and expectations concerning the safety level of veterinary pharmacovigilance could be different for human pharmacovigilance?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (140)</b>
No opinion	3	(1.7 %)	(2.1 %)
Strongly disagree	20	(11.6 %)	(14.3 %)
Agree	83	(48.3 %)	(59.3 %)
Strongly agree	34	(19.8 %)	(24.3 %)
N/A	32	(18.6 %)	-

As table 4.4.2 shows, the majority of respondents are positive about introducing a master file for pharmacovigilance or any other way of reducing the regulatory burden on authorisation holders. At sectorial level, the authorities and industry are very much in favour of such measures, whereas most veterinarians are merely 'somewhat in favour'.

<b>4.4.2 Would you favour the introduction of a masterfile for pharmacovigilance or any other means of reducing the regulatory burden of authorisation holders?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (139)</b>
Favour not at all	2	(1.2 %)	(1.4 %)
Favour not	2	(1.2 %)	(1.4 %)
Favour somewhat	69	(40.1 %)	(49.6 %)

Favour clearly	18	(10.5 %)	(12.9 %)
Favour very much	46	(26.7 %)	(33.1 %)
Do not know	2	(1.2 %)	(1.4 %)
N/A	33	(19.2 %)	-

On the question whether the participants in the consultation think that there are particular problems in the legislation for pharmacovigilance for SMEs (see table 4.4.3), it can be seen from the data that most of the respondents do not have a position on this particular issue. Among those who have an opinion, the majority think that there are problems.

<b>4.4.3 Do you think that there are particular problems in the legislation for pharmacovigilance for SMEs?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (130)</b>
Yes	42	(24.4 %)	(32.3 %)
No	11	(6.4 %)	(8.5 %)
Do not know	77	(44.8 %)	(59.2 %)
N/A	42	(24.4 %)	-

Finally, as regards the possibility of establishing a harmonised system for data collection on the sales and use of medicines in the EU, the majority of respondents are just somewhat in favour of the measure (see table 4.4.4). They are mainly veterinarians and representatives from the industry. Those who are clearly or very much in favour are the authorities and non-business organisations.

<b>4.4.4 Would you favour the introduction of a specific legal base for establishing harmonised systems for data collection on the sales and use of medicines in the EU?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (139)</b>
Favour not at all	4	(2.3 %)	(2.9 %)
Favour not	2	(1.2 %)	(1.4 %)
Favour somewhat	83	(48.3 %)	(59.7 %)
Favour clearly	27	(15.7 %)	(19.4 %)
Favour very much	18	(10.5 %)	(12.9 %)
Do not know	5	(2.9 %)	(3.6 %)
N/A	33	(19.2 %)	-

#### **4.5. The Distribution Channel**

A majority of the respondents (66%) agree or strongly agree (see table 4.5.1) that there is a need to standardise and harmonise the conditions for operators in the EU distribution channel. When the participants were asked if they would be in favour of standardisation by amending the European legal framework, the same results were obtained: a majority replied positively (see table 4.5.2).

<b>4.5.1 Do you consider that there is a need to standardise and harmonise the conditions for operators in the EU distribution channel</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (142)</b>
No opinion	7	(4.1 %)	(4.9 %)
Strongly disagree	31	(18 %)	(21.8 %)
Agree	83	(48.3 %)	(58.5 %)
Strongly agree	21	(12.2 %)	(14.8 %)
N/A	30	(17.4 %)	-

<b>4.5.2 If so, would you favour standardisation by amending the European legal framework?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (138)</b>
Favour not at all	28	(16.3 %)	(20.3 %)
Favour not	5	(2.9 %)	(3.6 %)
Favour somewhat	15	(8.7 %)	(10.9 %)
Favour clearly	70	(40.7 %)	(50.7 %)
Favour very much	16	(9.3 %)	(11.6 %)
Do not know	4	(2.3 %)	(2.9 %)
N/A	34	(19.8 %)	-

Most of the participants are very much in favour or clearly in favour of the prescription of medicines being standardised in the EU (see table 4.5.3), especially veterinarians, authorities and non-business organisations. Industry representatives are mainly not at all in favour.

<b>4.5.3 Would you be in favour of the prescription of medicines being standardised in the EU</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (142)</b>
Favour not at all	27	(15.7 %)	(19 %)
Favour not	5	(2.9 %)	(3.5 %)
Favour somewhat	9	(5.2 %)	(6.3 %)
Favour clearly	23	(13.4 %)	(16.2 %)
Favour very much	76	(44.2 %)	(53.5 %)
Do not know	2	(1.2 %)	(1.4 %)
N/A	30	(17.4 %)	-

Most respondents (60 %) consider that cross-border activities of the sector are hampered by the current rules (see table 4.5.4).

<b>4.5.4 Do you consider that cross-border activities, for example involving veterinarians active in two Member States, are hampered by the current rules?</b>
--



	Number of replies to the question	% of total replies to the consultation (172)	% of replies to the question (142)
Yes	103	(59.9 %)	(72.5 %)
No	24	(14 %)	(16.9 %)
Do not know	15	(8.7 %)	(10.6 %)
N/A	30	(17.4 %)	-

As far as counterfeit veterinary medicines are concerned, a majority agrees that they have penetrated the veterinary supply chain (see table 4.5.5). However, it needs to be emphasised that a number of participants strongly disagree with the above statement, especially stakeholders from the industry.

<b>4.5.5 Do you agree that counterfeit medicines have penetrated the veterinary supply chain?</b>			
	Number of replies to the question	% of total replies to the consultation (172)	% of replies to the question (139)
No opinion	31	(18 %)	(22.3 %)
Strongly disagree	25	(14.5 %)	(18 %)
Agree	80	(46.5 %)	(57.6 %)
Strongly agree	3	(1.7 %)	(2.2 %)
N/A	33	(19.2 %)	-

A lot of the respondents consider that there are risks to public health from the penetration of counterfeit medicines into the veterinary supply chain (see table 4.5.6).

<b>4.5.6 If so, do you consider that there are risks to public health from the penetration of counterfeit medicines into the veterinary supply chain?</b>			
	Number of replies to the question	% of total replies to the consultation (172)	% of replies to the question (132)
No opinion	6	(3.5 %)	(4.5 %)
Strongly disagree	4	(2.3 %)	(3 %)
Agree	102	(59.3 %)	(77.3 %)
Strongly agree	20	(11.6 %)	(15.2 %)
N/A	40	(23.3 %)	-

When the participants in the consultation were asked about whether they consider counterfeiting of veterinary medicinal products to be a problem for animal health and/or public health in the EU, a large proportion (40 %) said they did not have an opinion (table 4.5.7).

<b>4.5.7 Do you consider counterfeiting of veterinary medicinal products to be a problem for animal health and/or public health in the EU?</b>			
	Number of replies to the question	% of total replies to the consultation (172)	% of replies to the question (143)

No opinion	68	(39.5 %)	(47.6 %)
Strongly disagree	22	(12.8 %)	(15.4 %)
Agree	36	(20.9 %)	(25.2 %)
Strongly agree	17	(9.9 %)	(11.9 %)
N/A	29	(16.9 %)	-

Notwithstanding the clear positions on counterfeit medicines, the great majority of respondents (9578%) indicated that they had neither quantitative nor qualitative data on counterfeit veterinary medicinal products (see table 4.5.8). It can be concluded that there is a consensus among stakeholders (129 out of 131 respondents to this question) that legislative measures are necessary to tackle counterfeit veterinary medicinal products (table 4.5.9).

<b>4.5.8 Do you have qualitative or quantitative data on counterfeit veterinary medicinal products?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (140)</b>
Yes	6	(3.5 %)	(4.3 %)
No	134	(77.9 %)	(95.7 %)
N/A	32	(18.6 %)	-

<b>4.5.9 Do you think that legislative measures are necessary to tackle counterfeit veterinary medicinal products?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (145)</b>
Yes	129	(75 %)	(89 %)
No	2	(1.2 %)	(1.4 %)
Do not know	14	(8.1 %)	(9.7 %)
N/A	27	(15.7 %)	-

The majority (76 %) of participants in the consultation agree or strongly agree that issues such as internet trade, mail order selling or parallel import should be addressed in the revision of the legal framework for veterinary medicines (table 4.5.10). In this connection, as we can see from table 4.5.11, most of the participants consider that the legal framework should be supplemented with specific requirements on these aspects.

<b>4.5.10 Should the issues of internet trade, mail order selling or parallel import be addressed in the revision of the legal framework for veterinary medicines?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (143)</b>
No opinion	2	(1.2 %)	(1.4 %)
Strongly disagree	9	(5.2 %)	(6.3 %)
Agree	53	(30.8 %)	(37.1 %)
Strongly agree	79	(45.9 %)	(55.2 %)
N/A	29	(16.9 %)	-

<b>4.5.11 Do you consider that the legal framework should be supplemented with specific requirements on internet trade, mail order selling or parallel import?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (142)</b>
Yes	129	(75 %)	(90.8 %)
No	9	(5.2 %)	(6.3 %)
Do not know	4	(2.3 %)	(2.8 %)
N/A	30	(17.4 %)	-

#### **4.6. The use of drugs not in accordance with the summary of product characteristics (off-label use)**

About 86 % of respondents considered the description in the public consultation accurate (see table 4.6.1). A minority (34 replies; 19 %) considered that off-label use of medicines was too common in the EU; the majority (99 replies; 58 %) did not agree with this statement (table 4.6.2). This last group consisted mostly of veterinarians and respondents from the pharmaceutical industry.

<b>4.6.1 Is the above an accurate description of the situation?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (151)</b>
Yes	148	86.05 %	98.01 %
No	3	1.74 %	1.99 %
N/A	-	12.21 %	-

<b>4.6.2 Do you consider that off-label use of medicines is too common in the EU?</b>			
	<b>Number of replies to the question</b>	<b>% of total replies to the consultation (172)</b>	<b>% of replies to the question (152)</b>
No opinion	19	11.05 %	12.50 %
Strongly disagree	99	57.56 %	65.13 %
Agree	28	16.28 %	18.42 %
Strongly agree	6	3.49 %	3.95 %
N/A	-	11.63 %	-

Respondents clarified that limited data existed on off-label use (only 14 out of 147 respondents reported that they had such data) (see table 4.6.3). Some qualitative data were provided on rabbits, horses, poultry and aquaculture for certain Member States. One authority provided data on the extent veterinarians had to rely on veterinary medicines imported from other Member States for use under the cascade. It appeared that the vast majority of

applications for importation were for pets. One pharmaceutical company stated that 25-30 % of suspected adverse reactions reported involved off-label use.

<b>4.6.3 Do you have quantitative or qualitative data on off-label use?</b>			
	<b>Number of replies</b>	<b>% of total replies to the questionnaire (172)</b>	<b>% of replies to the question (147)</b>
Yes	14	8.14 %	9.52 %
No	133	77.33 %	90.48 %
N/A	-	14.53 %	-

Most of the respondents (115 replies; 67 %) considered off-label use a potential hazard (see table 4.6.4). However, a substantial minority (32 replies; 19 %) did not agree with this statement; these were mainly producers (10 replies), veterinarians (6 replies) or from industry (5 replies).

<b>4.6.4 Do you consider off-label use a potential hazard for animal and /or public health?</b>			
	<b>Number of replies</b>	<b>% of total replies to the questionnaire (172)</b>	<b>% of replies to the question (151)</b>
Yes	115	66.86 %	76.16 %
No	32	18.60 %	21.19 %
Do not know	4	2.33 %	2.65 %
N/A	-	12.21 %	-

A minority (47 replies; 27 %) considered it appropriate to exclude certain medicines from off-label use (see table 4.6.5). These were mainly authorities (17 replies), producers (10 replies), veterinarians (10 replies) and industry (5 replies). Most of the respondents (104 replies, 69 %) did not agree with the statement to exclude certain medicines from off-label use.

<b>4.6.5 Would you consider it appropriate to exclude certain medicines from off-label use?</b>			
	<b>Number of replies</b>	<b>% of total replies to the questionnaire (172)</b>	<b>% of replies to the question (151)</b>
No opinion	12	6.98 %	7.95 %
Strongly disagree	92	53.49 %	60.93 %
Agree	39	22.67 %	25.83 %
Strongly agree	8	4.65 %	5.30 %
N/A	-	12.21 %	-

Many respondents (86 replies) took the opportunity to put forward proposals for amending the legal framework concerning off-label use.

#### 4.7. Harmonisation of already authorised veterinary products

Regarding this key issue, the vast majority of the respondents agree with the description of the situation done by the Commission (see table 4.7.1).

<b>4.7.1 Do you agree with the description of the issue?</b>			
	<b>Number of replies</b>	<b>% of total replies to the questionnaire (172)</b>	<b>% of replies to the question (141)</b>
Yes	139	(80.8%)	(98.6%)
No	2	(1.2%)	(1.4%)
N/A	31	(18%)	-

However, when they were asked if they consider necessary to update and to harmonise the already authorised medicines, the majority (52%) disagreed (see table 4.7.2), mainly consisting of participants from the industry and veterinaries. The authorities, even if they are divided in their opinions, most of them are the ones who agree or strongly agree with the idea of updating and harmonising the already authorised veterinary medicines. Respondents from non business organisations are equally divided between agree and disagree.

<b>4.7.2 Do you consider it necessary to update and to harmonise already authorised medicines?</b>			
	<b>Number of replies</b>	<b>% of total replies to the questionnaire (172)</b>	<b>% of replies to the question (142)</b>
No opinion	5	(2.9%)	(3.5%)
Strongly disagree	90	(52.3%)	(63.4%)
Agree	36	(20.9%)	(25.4%)
Strongly agree	11	(6.4%)	(7.7%)
N/A	30	(17.4%)	-

A majority of respondents agreed to a risk-based harmonisation (to update and to harmonise already authorised medicines differently according to the public health risks involved) (table 4.7.3).

<b>4.7.3 If a procedure were established to update and to harmonise already authorised medicines, would you consider it appropriate to apply the procedure differently according to the public health risks involved or to other criteria (e.g. to prioritize the harmonisation of products with high public health concern)?</b>			
	<b>Number of replies</b>	<b>% of total replies to the questionnaire (172)</b>	<b>% of replies to the question (142)</b>
Yes	131	(76.2%)	(92.3%)
No	11	(6.4%)	(7.7%)
N/A	30	(17.4%)	-

The majority of the respondents (57%) preferred a compulsory approach to update and to harmonise already authorised medicines (see table 4.7.4), consisting mainly of veterinarians, authorities and non business organisations.

<b>4.7.4 If a procedure were established to update and to harmonise already authorised medicines, would you prefer a compulsory approach?</b>			
	<b>Number of replies</b>	<b>% of total replies to the questionnaire (172)</b>	<b>% of replies to the question (143)</b>
No opinion	10	(5.8%)	(7%)
Strongly disagree	34	(19.8%)	(23.8%)
Agree	92	(53.5%)	(64.3%)
Strongly agree	7	(4.1%)	(4.9%)
N/A	29	(16.9%)	-

#### **4.8. New needs and new challenges**

The aim of this last chapter of the public consultation is to see if the participants perceived that there is a real need to change the legal framework to better respond to new veterinary needs, new circumstances and new technologies.

In reply to this, as we can see in table 4.8.1, most of the respondents (81%) agree that this issue needs to be addressed in the review of the veterinary medicinal legislation.

<b>4.8.1 Should this issue of new needs and new challenges be addressed in the review?</b>			
	<b>Number of replies</b>	<b>% of total replies to the questionnaire (172)</b>	<b>% of replies to the question (146)</b>
No opinion	6	(3.5%)	(4.1%)
Strongly disagree	0	(0%)	(0%)
Agree	123	(71.5%)	(84.2%)
Strongly agree	17	(9.9%)	(11.6%)
N/A	26	(15.1%)	-

Regarding the development and production of medicines through new technologies, when the stakeholders were asked if they agree that there are difficulties to assess them, more agree (44%) than disagree (1%). It is important to note that about 40% of the respondents do not have a fixed opinion on the subject.

<b>4.8.2 Do you agree that there are difficulties in the assessment of medicines developed or produced by new technologies?</b>			
	<b>Number of replies</b>	<b>% of total replies to the questionnaire (172)</b>	<b>% of replies to the question (146)</b>
No opinion	69	(40.1%)	(47.3%)
Strongly disagree	2	(1.2%)	(1.4%)

Agree	65	(37.8%)	(44.5%)
Strongly agree	10	(5.8%)	(6.8%)
N/A	26	(15.1%)	-

Not many participants in the public consultation, just about 20%, had specific proposals how to authorise veterinary medicinal products urgently in the event of an emergency. Several participants provided concrete proposals in relation to new needs and challenges.

## Annex 1 Public consultation document

# Better regulation of veterinary pharmaceuticals: how to put in place a simpler legal framework, safeguarding public and animal health while increasing the competitiveness of companies

## 1. ABOUT THE CONSULTATION

### 1.1. What is the purpose of this consultation?

In the context of co-decision procedure concerning the proposal for a Regulation on residue limits of pharmaceutical products in foodstuffs the Commission made the following declaration<sup>1</sup>:

"The Commission is aware of concerns expressed by citizens, veterinarians, Member States and the animal health industry as regards the directive laying down the rules for the authorization of veterinary medicinal products, in particular the importance of addressing existing problems linked to the availability of veterinary medicinal products and the use of medicinal products in species for which they are not authorized and any disproportionate regulatory burden hampering innovation, whilst ensuring a high level of consumer safety with respect to food or animal origin. The Commission points out those positive steps are being taken in this direction such as the simplification of the rules on variations of veterinary medicinal products and this review of the legislation on maximum residue limits in food. In addition, in order to address the objectives of consumer safety and animal health protection, competitiveness of the veterinary industry including SMEs and reduction of administrative burden, the Commission will present in 2010 an assessment of the problems in the application of the veterinary medicinal products directive with a view to making, where appropriate, legal proposals".

By means of this public consultation, the Directorate General for Health and Consumers (DG Health and Consumers) intends to consult all stakeholders on their views on the strengths and weaknesses of the current legal framework for veterinary medicinal products and how it could be improved. Your comments will help DG Health and Consumers to draft the impact assessment on a revision of the veterinary legal framework and, where appropriate, to draft proposals to change the legal framework. It is emphasised that the public consultation relates to the current legal framework for veterinary medicinal products. Therefore the scope of the public consultation includes Directive 2001/82/EC, Regulation (EC) No 726/2004 and all other legislation directly relating to veterinary medicines. Veterinary medicines cover also biologicals, for example vaccines.

It is important that any contribution should be supported, where possible, by detailed evidence. In particular, we would like to receive as many quantitative data, studies and evaluations as possible which will allow us to better describe the current situation and to analyse the impact of potential changes. However, if you have only descriptive information this can still be very useful to us.

It needs to be emphasised that the purpose of this consultation paper is not to outline detailed legal amendments. The paper provides a basis for discussion on key issues and key items where a need and/or possible amendments of the legal framework have already been identified by stakeholders (see sections 3 and 4). However, stakeholders are asked to comment on all issues related to the current legal framework for veterinary medicinal products, and to submit any general or detailed comment or proposal to change the legal framework. We would especially like



to specially invite contributions from stakeholders on the key issues set out in this consultation paper.

The consultation paper is structured as follows:

- Section 1 relates to the consultation (explaining how and by when to submit consultation responses and the next steps).
- Section 2 provides a brief guide to the legal framework for veterinary medicinal products, as well as a summary of strengths and weaknesses of the current framework as pointed out by stakeholders.
- Section 3 sets out the main objectives and options for a review of the legal framework in relation to the Commission's declaration.
- Section 4 presents the key issues where possible amendments of the legal framework have been already identified by stakeholders.
- Section 5 relates to the general information as requested of submitting parties.

Through this public consultation, DG Health and Consumers is committed to ensure that all stakeholders can make their views known on this important issue.

This document does not represent an official position of the European Commission. Based on the results of the public consultation, among others, DG Health and Consumers will prepare a report of the impact assessment on a revision of the veterinary legal framework.

## 1.2. Who is consulted?

Contributions are invited from all stakeholders and interested parties dealing with medicines for veterinary use. Stakeholders who are not established within the European Union are likewise invited to comment. Comments from Small and Medium-sized Enterprises (SMEs) involved in the pharmaceutical sector are especially welcomed.

## 1.3. How can I contribute?

Submitting parties should indicate whether they are a citizen (name, telephone number, email address, Member State / country), non-business organisation, business organisation, enterprise or a public authority. In the case of a business organisation or enterprise, please indicate the type of stakeholder (farmer, veterinarian, manufacturer, wholesaler, pharmaceutical industry, importer, researcher, other) and which countries your enterprise or organisation covers. In the case of business organisation or enterprise, please indicate the yearly turnover and number of employees in order to determine whether your business organisation or enterprise falls within the Community definition of a small and medium-sized enterprise (i.e., <50m EUR yearly turnover and, cumulatively, <250 employees).

An acknowledgement of receipt will be issued for each contribution received, within five working days.

Contributions will be made publicly available on the 'Pharmaceuticals' website of the Commission<sup>2</sup> once the consultation period is over. If you do not wish your contribution to be made public, please indicate this clearly and specifically in your submission. In this case, only an indication of the contributor will be disclosed.

Professional organisations are invited to register in the Commission's Register for Interest Representatives (<http://ec.europa.eu/transparency/regrin/>) set up as part of the European Transparency Initiative in order to provide the Commission and the public at large with information about the objectives, funding and structures of interest representatives.

## 1.4. What will happen next?

All contributions will be carefully analysed. A summary of the outcome of the consultation will be published on the 'Pharmaceuticals' website of the European Commission and also sent directly to all contributors. The results of the consultation will be utilised for the impact assessment report on a revision of the legal framework for veterinary medicinal products. For regularly updated information on the next steps of the impact assessment exercise, please consult the webpage of SANCO Pharmaceuticals.

## 2 LEGAL FRAMEWORK FOR VETERINARY MEDICINAL PRODUCTS: A BRIEF DESCRIPTION AND THE PERCEIVED STRENGTHS AND WEAKNESSES

### 2.1 Context

Within the European Union veterinary medicinal products are regulated by legislation throughout their entire lifetime on the basis of scientific expertise. The primary objective of this legislation is to protect public and animal health on the basis of scientific evaluation. A secondary objective is the completion of the internal market for pharmaceutical products.

In order to ensure the quality, safety and efficacy of medicines, a veterinary medicinal product may only be placed on the market in the Community when a marketing authorisation has been issued. Throughout the lifetime of veterinary medicinal products, animal health companies are subject to harmonised pharmacovigilance requirements to monitor adverse reactions to a medicine and/or new side effects. The legal framework provides a special, simplified registration procedure for homeopathic medicinal products. This procedure takes into account the particular characteristics of homeopathic products, such as the very low level of active substances they contain and the difficulty of applying to them the conventional statistical methods. Comments are welcome on this specific procedure for homeopathic products.

For almost 20 years, veterinary medicinal products in the EU were regulated under Directive 81/851/EEC and Directive 81/852/EEC. In 1990, Regulation (EC) No 2377/1990 entered into force, introducing the concept of maximum residue limits. The Directive 81/851/EEC and Directive 81/852/EEC were supplemented in 1993 by Regulation (EEC) No 2309/93, which established the European Medicines Evaluation Agency (EMA) and the centralised Community procedure for both human and veterinary medicines. The Directive 81/851/EEC and Directive 81/852/EEC were merged in the Community code of Directive 2001/82/EC<sup>3</sup> which provided the legal environment for the authorisation, manufacturing, marketing, distribution and use of veterinary medicinal products. A major revision of this framework was carried out in 2004 by Regulation (EC) No 726/2004<sup>4</sup> and Directive 2004/28/EC<sup>5</sup>. Subsequently, parts of the legal environment were further amended: this included the data to be submitted in order to obtain marketing authorisation for a veterinary medicinal product<sup>6</sup> and the procedure for amendments in relation to authorised products<sup>7</sup>. The Commission also decided to assist small and medium-sized enterprises in promoting innovation and the development of new veterinary products<sup>8</sup>. A last major revision was introduced in 2009 by Regulation (EC) No 470/2009<sup>9</sup> replacing Regulation (EC) No 2377/1990 on maximum residue limits. This new regulation was developed with a view to increasing the availability of veterinary medical products.

The EU regulatory legal frameworks for veterinary and human medicines have developed in parallel over the years and have much in common. This provides a number of advantages in terms of ease of understanding and adoption, interpretation and case-law. However, the nature or the needs of the veterinary context may require a different approach to be adopted than for human medicines. For example, for veterinary medicines administered to food producing animals the regulatory environment must ensure that residues of veterinary medicines do not pose a risk to consumers.

The spread of antimicrobial resistance is a major threat to both public health and animal health. This issue is currently being debated at various levels<sup>10</sup>. Any result that has relevance for this review should be introduced in the process for implementing the Commission's declaration. In the public consultation this horizontal issue is included as part of several key issues.

## 2.2 General strengths and weaknesses of the legal framework as perceived by stakeholders

The regulatory framework is considered to have helped to enhance the quality, efficacy and safety of the medicines to animals, consumers of foodstuffs, users of medicines and the environment. It has also played an essential role in establishing consumer confidence in veterinary pharmaceutical products and making progress towards a single market for veterinary medicines. However, the framework is perceived by stakeholders to have become complex with its mixture of centralised, decentralised and national authorisations procedures and responsibilities plus the consequent increase in the time, cost and uncertainty of developing new veterinary medicinal products. Companies indicate that they spend considerable sums of money to keep existing products on the market and continue to raise concerns over unnecessary regulatory burdens, e.g. those which are caused by requirements and conditions in the legal framework that are seen as unnecessary or - while a harmonised regulatory environment exists for the authorisation and placing on the market of veterinary medicinal products - divergences in the implementation of Community legislation by Member States.

Companies also point out that there are not enough incentives in place for extending the scope of existing medicinal products on the market and also for developing new products. The general view is that the regulatory framework has not delivered the positive impact on the availability of authorised veterinary medicinal products where possible and as required. The problem is particularly striking where the market is small and the expected return on investment for companies is low. First, small markets exist for those disease conditions which are rarely encountered. Second, small markets exist for those species where the number of animals, birds, fish or insects (bees) is comparatively small and insufficient in the EU or in specific geographical areas to justify the costs for the development and authorisation of veterinarian medicines. Other terms often used to describe these small markets are "minor species" and "minor uses". For some specific animal species and diseases the possibilities of treatment with authorised medicines are limited. This poses significant problems for animal owners, farmers, producers of aquatic food and veterinarians. For producers of foodstuffs, the risks of the production process increase.

Veterinarians are faced with situations where there is no authorised veterinary medicine available and they may consider resorting to off-label use of medicines in order to treat the disease. The shortage of authorised medicines may also have implications for public health either through the inability to control zoonotic diseases in animals, through the off-label use of veterinary medicines or the use of illegal substances with the attendant risks of exposing consumers to potentially harmful drug residues in foodstuffs.

Another issue is the incorrect functioning of the internal market. For most of the authorised veterinary medicinal products marketing authorisations seem to have been granted by national authorities, and the existing mechanism for recognizing the assessment of veterinary medicinal products by other Member States (mutual recognition procedure) has been only partially successful. Delays are identified by stakeholders in the assessment process due to shortcoming and backlogs in national approval systems and discrepancies are perceived with regard to the national implementation of the EU regulatory framework in the individual Member States. Therefore, despite the review of the legislation in 2004 and other initiatives undertaken, in practice a genuine single market for veterinary medicinal products does not seem to be a reality. Lastly, stakeholders raised concerns that the particular characteristics of the veterinary sector are not sufficiently integrated in the framework and that it does not contain enough incentives to stimulate innovation, in particular incentives to stimulate the development of new veterinary medicinal products.

## 3 SCOPE, MAIN OBJECTIVES AND OPTIONS OF A REVISION OF THE LEGAL FRAMEWORK FOR VETERINARY MEDICINAL PRODUCTS

The Commission's declaration (see paragraph 1.1) states that an assessment has to be provided of the problems in the application of the veterinary medicinal products directive. The scope of this public consultation and the review will be the regulatory framework (the veterinary directive and

all other relevant regulatory documents) concerning veterinary medicinal products. This will enable the Commission with the possibility to receive the information and to make, where appropriate, legal proposals for addressing the concerns expressed by citizens, non-governmental organizations, veterinarians, enterprises active in the food chain, Member States, the animal health industry and other interested parties in relation to the legal framework for veterinary medicinal products.

The objectives of the review of the legal framework are, without compromising public and animal health, as follows: (1) to increase the availability of veterinary medicinal products, (2) to decrease administrative burden and (3) to improve the functioning of the internal market for veterinary medicinal products. The policy options are structured into three demarcation fields: specific features of the veterinary sector, administrative burden and single market (see table 1). It should be noted that a combination of various options will be probably required in order to adequately address the weaknesses and problems of the current legal framework (see paragraph 2.2).

Table 1. Policy options

Fields	1. Specific features of the veterinary sector	2. Administrative burden	3. Single market
Policy options	1.1 Unchanged policy	2.1 Unchanged policy	3. 1 Unchanged policy
	1.2. Streamlining and harmonising off-label use	2.2 Rationalisation and simplification of requirements and conditions in the production, marketing and use of veterinary medicines	3.2 Revising the system for new market authorisations 3.2.1 Each competent authority decides for the whole EU-territory: each authorisation of a veterinary medicine, regardless of the procedure and the competent authority that issues it, will be valid throughout the EU 3.2.2 Centralised authorisation: one competent authority will have the competence to issue authorisations for all types of veterinary medicinal products valid throughout the EU 3.2.3 Voluntary automatic recognition: Some Member States can decide to automatically recognise decisions of competent authorities in other Member States 3.2.4 Best use of current procedures
	1.3 Better prepared for new needs	2.3 To align national requirements and conditions and administrative provisions, while allowing national/regional flexibility in duly justified cases	
	1.4 Broaden list of animal species for which specific conditions apply concerning the authorisation of veterinary medicinal products	2.4 Best use of resources in the EU by competent authorities	
	1.5 Better incentives for the veterinary pharmaceutical industry to develop veterinary medicines for small markets	2.5 Better use of modern information technology	3.3 Free movement of existing, authorised products in the EU
	1.6 Intellectual property tailored to veterinary sector		
	1.7 Assistance to undertakings that will apply for market authorisation and produce veterinary products for		

	small markets		
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On the basis of these objectives and options DG Health and Consumers is preparing an assessment of the possible impacts. This includes an analysis of the likely impacts of the main options and an examination of possible synergies and trade-offs. The results of the public consultation, as indicated earlier, will be carefully considered and included in the report of the impact assessment.

## 4 KEY ISSUES TO BE DISCUSSED

It is important to emphasise the difference between key issues and the three demarcation fields as included in Part Three of this public consultation. The demarcation fields are used to structure the policy options. The key issues in this fourth part of the public consultation are subjects on which the Commission specifically invites interested parties to provide a contribution and which may fall within the scope of one or more policy options as included in Table 1. Therefore, the information provided in the contribution could be applied for more than one policy option.

- 
1. Communication from the Commission to the European Parliament pursuant to the second subparagraph of Article 251(2°) of the EC Treaty concerning the common position of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, and repealing Regulation (EEC) No 21377/90, COM (2008)912, 08.01.2009
  2. See [SANCO pharmaceuticals website](#)
  3. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, OJ L311, 28.11.2001, p.1.
  4. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p.1.
  5. Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products, OJ L136, 30.4.2004, p.58.
  6. Commission Directive 2009/9/EC of 10 February 2009 amending Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use. OJ L 44, 14.2.2009, p.10.
  7. Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products. OJ L 334, 12.12.2008, p.7.
  8. Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-size enterprises. OJ L 329, 16.12.2005, p.4.
  9. Regulation (EC) No 470 /2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council. OJ L 152, 16.6.2009, p.11.
  10. Council Conclusions on Antimicrobial Resistance (AMR) adopted during the 2867th Employment, Social Policy, Health and Consumer Affairs Council meeting on 10 June 2008  
At the EU-US summit of 3 November 2009 was agreed to establish an EU-US transatlantic taskforce on urgent antimicrobial resistance issues focused on appropriate therapeutic use of antimicrobial drugs in the medicinal and veterinary communities, prevention of both healthcare- and community-associated drug-resistant infections, and strategies for improving the pipeline of new antimicrobial drugs, which could be better addressed by intensified cooperation between us  
Joint opinion on antimicrobial resistance (AMR) focused on zoonotic infections (ECDC, EFSA, EMEA, SCENIHR) 2009

Analysis of the baseline survey on the prevalence of methicillin resistant *Staphylococcus aureus* (MRSA) in holdings with breeding pigs, in the EU, 2008. (EFSA) 2009  
Staff working paper of the services of the Commission a on antimicrobial resistance (18 November 2009)  
Assessment of the Public Health significance of methicillin resistant *Staphylococcus aureus* (MRSA) in animals and foods (EFSA) 2009  
Reflection paper on MRSA in food producing and companion animals in the EU (EMEA) 2009  
Revised reflection paper on the use of 3rd and 4th generation cephalosporins in food-producing animals in the EU (EMEA) 2009  
The opinion of the EFSA BIOHAZ Panel on food-borne antimicrobial resistance as a biological hazard (EFSA) 2008  
Public Statement on the use of (fluoro)quinolones in food-producing animals in the EU: Development of resistance and impact on human and animal health (EMEA) 2007

## 4.1 Key issue N° 1: Data exclusivity

### 4.1.1 The issue

Regulatory authorities require pharmaceutical companies to submit extensive data establishing the safety, quality and efficacy of a new drug before they approve it for sale. These data are the result of many years of research and clinical trials and are expensive to produce. In the current legal framework<sup>11</sup> an applicant shall **not** be required to provide the results of a safety and residue test or of the pre-clinical and clinical trials if it can be demonstrated that the medicinal product is a generic of a reference medicinal product. Therefore, a generic company can rely on the data of a reference medicinal product (original product) for the marketing authorisation. However, tests assessing the potential risks posed by medicinal product for the environment<sup>12</sup> also have to be provided by the generic applicant<sup>13</sup>.

When a company has a medicine containing an active substance that is authorised, any additional species, pharmaceutical form or different route of administration subsequently authorised for that company for a product containing that active substance belongs to the same global marketing authorisation. The period of exclusivity (including the extension of this period to another food-producing species) begins with the first authorisation. Thus, the period of exclusivity for any additional investment is directly linked to the granting of the initial authorisation.

Currently the term of exclusivity is ten years (13 years in the case of medicinal products for fish or bees). The ten-year period is extended by one year for each extension of the marketing authorisation to another food-producing species (with a maximum of 13 years). This extension to another food-producing species has to take place within the five years following the granting of the initial marketing authorisation. As indicated above, the term of exclusivity is currently 13 years in the case of medicinal products for fish or bees. For other minor food-producing species it was expected that veterinary medicinal products would be derived from existing medicinal products for major food-producing species, and consequently an additional year of exclusivity was included in the legal framework.

Data exclusivity as provided by pharmaceutical legislation is one way to reward successful product research and development. In general the patent system<sup>14</sup> is regarded the primary mechanism to reward and protect innovation, and the pharmaceutical sector relies heavily on patents to protect inventions. Stakeholders point out that the current framework of data exclusivity does not provide sufficient incentives for innovation in the animal health sector. In particular it has been pointed out that the current additional period of data exclusivity for each extension of the authorisation to another food-producing species does not provide a sufficient return on investment. Although the investment in an additional species may be smaller than for the first species, the commercial target market of the additional species will also be smaller and thus it would take longer to obtain a return on investment.

National marketing authorisations of veterinary medicinal products with the same active pharmaceutical ingredient have often different terms in Member States. Companies can choose which reference products to depend on. This implies that the Summary of Product Characteristics (SPC) for a generic product being marketed in Member States may differ significantly from the originator product already authorised in a given Member State.

### 4.1.2 Consequences

Data exclusivity prevents originator companies from having to face competition from generics during the period of exclusivity and gives an opportunity to benefit financially from the

innovation. This provides an incentive for innovation, for example to develop products for small markets. Generic medicines contain well-known substances. Therefore applicants can depend for the marketing authorisation partially on existing data and there is no need to repeat (animal) testing and trials. It could be argued that competition of generics should be promoted for the interest of the users of medicines in obtaining low price medicinal products. On the other hand data exclusivity provides companies an incentive for innovation. The issue is to balance the goal of improving access to low-cost veterinary medicinal products while preserving sufficient incentives needed for innovation. An exclusivity period that is too long might involve unnecessary high costs for medicines, while too short a period might involve an inappropriate incentive for innovation and consequently lead to less development of new medicines. For older reference products the existing data may not be fulfilling the expectations of recent evaluation standards. This means that Member States may have to authorise a generic product on another basis than the current original one. This situation could result in harmonisation across Member States of the SPC of the generic but also in disharmony within a given Member State between the generic SPC and the SPC of the original product. Some interested parties consider that this situation may create a risk that veterinary products not being used appropriately and, consequently, it may have an impact on animal or public health. It must be emphasised, however, that the reference veterinary medicinal products have been assessed in the past and were found to be safe and efficacious at the time.

#### 4.1.3 Options to address this issue

Exclusivity conditions could be adjusted to provide the appropriate incentives. This could be done across the board in order to provide a better incentive for innovation or specifically for small markets. Longer periods of exclusivity could be provided in the case of markets for which there is no reasonable expectation of the pharmaceutical companies recovering research and development costs.

Tests assessing the potential risks posed by medicinal products for the environment must also be provided by the generic applicant. Potential environmental risks posed by medicinal products mostly apply to a range of authorised products. Therefore it could be efficient to generate these data as part of a non-individual approach and the use of a monograph<sup>15</sup> system could be evaluated. Another option could be to no longer differentiate between the tests for environmental risks and other data. This would imply that for all data the same data exclusivity rules would apply.

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11. Article 13 of Directive 2001/82/EC specifies that the applicant for marketing authorisation shall not be required to provide the results of safety and residue tests or of the pre-clinical and clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 5 for not less than eight years in a Member State of the Community.

12. See Article 12 (3) (j) of Directive 2001/82/EC for this information requirement.

13. For further details it is recommended to consult Notice to Applicants Veterinary Medicinal Products Volume 6c, Guidance on the Assessment of environmental risks of veterinary medicinal products.

14. Patent protection gives the innovator an exclusive right to the commercial exploitation of the invention for a certain period of time. In Europe, patent protection may be obtained for up to 20 years.

15. A monographs provide a harmonised approach to the scientific assessment of medicinal product in the EU, and the Member States shall take them into account when they examine an application relating to a product for which a Community monograph has been established.

Do you agree with the description of the issue (optional)

Yes

No

Do not know

Please indicate your satisfaction with the level of data protection provided by the current legal framework (optional)

- No opinion
- Very unsatisfactory
- Unsatisfactory
- Satisfactory
- Very satisfactory

Do you have quantitative or qualitative data showing the impact of the current data exclusivity period on innovation (yes, no) If so please provide estimate of impact? (optional)

Yes  No

Do you have data on effective protection periods of originator products calculated from the authorisation of the originator until the first authorisation of a generic? (compulsory)

- Yes
- No

If so, please provide data. (optional)



Do you agree that generic companies provide for a competitive market within the veterinary pharmaceutical industry that is reflected in the pricing structure of veterinary medicines which is passed on to the end user? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Do you consider that the current data exclusivity period in the legal framework strikes the appropriate balance between innovation and competition? (optional)

- No opinion
- Very unsatisfactory
- Unsatisfactory
- Satisfactory
- Very satisfactory

Please substantiate your reply. (optional)

Would you agree to increase the general period of data protection of 10 years? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Do you consider the current additional data exclusivity period of one year for each extension of the authorisation to another food-producing species appropriate? (optional)

- No opinion
- Very unsatisfactory

- Unsatisfactory
- Satisfactory
- Very satisfactory

Please substantiate your reply. (optional)

Do you consider that in data protection rules there are particular burdens in relation to the features of SMEs? (optional)

- Yes
- No
- Do not know

Would you be in favour of major product developments (for example extending the authorisation to additional animal species, new formulations of the substance) being subject to their own period of exclusivity (i.e. not being part of the global marketing authorisation for the product containing that active substance)? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly

- Favour very much
- Do not know

Do you consider the current general market exclusivity period of 13 years for fish and bees appropriate? (optional)

- Yes
- No
- Do not know

Please substantiate your reply (optional)

Should the data exclusivity period of 13 years for bees and fish be extended to other species? (optional)

- No opinion
- Very unsatisfactory
- Unsatisfactory
- Satisfactory
- Very satisfactory

If so, please indicate the species which in your opinion require the same approach as bees and fish. Please substantiate your reply, in particular providing the reasons to include new types of species. (optional)

Would you be in favour of amending the condition that only in a time period of five years following the granting of the initial marketing authorisation an extension of the period of market exclusivity can be obtained? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Should specific intellectual property incentives be developed for small markets? (optional)

- Yes
- No
- Do not know

Do you have concrete proposals (to amend the legal framework) concerning intellectual property rights? (optional)

Do you agree that generics increase the availability of veterinary medicines (e.g. in smaller Member States in which the original product was not marketed)? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Do you have data to substantiate that generics improve availability of veterinary medicinal products? (optional)

Do you think an applicant should be allowed to use the data in relation the potential risks posed by medicinal product for the environment (like for the results of safety and residue test or of the pre-clinical and clinical trials)? (optional)

- Yes
- No
- Do not know

Would you favour a monograph system for environmental risks? (optional)

- Favour not at all
- Favour not

- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Generic veterinary products may be based on reference products that have been on the market for a long time, and the approval of these reference products will have taken place not according to current requirements. Do you consider that generic veterinary products based on these "old" reference products could pose a risk for public or animal health? (optional)

- Yes
- No
- Do not know

Do you have concrete proposals (to amend the legal framework) in relation to generics? (optional)



## 4.2 Key issue N° 2: Authorisation procedure

### 4.2.1 The issue

There are several procedures for authorisation in the EU. The centralised procedure results in a single marketing authorisation (called a 'Community marketing authorisation') that is valid across the EU; the European Medicines Agency (EMA) is responsible for the scientific assessment of the application. The centralised procedure is compulsory for certain categories of medicines (for example medicines derived from biotechnology processes). National marketing authorisations result in a marketing authorisation only for the Member State concerned or they can be valid for several Member States under a mutual recognition procedure or a decentralised procedure. In these procedures the marketing authorization in one Member State will be recognised by the other Member States. The applicant must submit an application in all Member States concerned. Scientific assessment and management decisions are made by national authorities.

Although there is a harmonised regulatory environment in the EU for the authorisation and placing on the market of veterinary medicinal products, differences between Member States in interpreting the legislative framework for veterinary medicinal products, as well as the existence of numerous national requirements for authorisation, result in a situation where enterprises are confronted by different rules and interpretations in different countries. However, animals treated with veterinary medicines and their foodstuffs can move unhindered within the internal market even if the veterinary products themselves cannot. It should also be noted that the authorisation systems have become very complex. It is important to note that during the last 8 years the decentralised procedure appears to have become more attractive for companies, as there has

been a substantial increase in the number of applications for this procedure. In general, interest in a centralised procedure is limited. This is probably due to the fact that, for the most part, the animal health industry is not interested in launching its product on all national European markets. Thus, the various, parallel authorisation procedures seem to cater for specific needs of companies by offering various routes to obtain marketing authorisation.

Under the current legal framework the authorisation of a medicine shall be refused if it is clear that the balance of risks and benefits is unfavourable. A risk is defined as any risk relating to the quality, safety and efficacy of the veterinary medicinal product as regards animal or human health. However, the current legislation does not lay down any requirement to perform a risk-benefit assessment which also takes into consideration the indirect risks related to the development of antimicrobial resistance. Neither does the legal framework contain a clear basis for refusing a marketing application and/or certain indications where authorisation of an antimicrobial might pose an indirect risk to animal or human health, such as risks relating to the development and/or the prevalence of antimicrobial resistance. Nor does the legal framework provide a specific legal basis to restrict the use of certain antimicrobials in veterinary medicines which are critical in human medicine.

#### 4.2.2 Consequences

Enterprises consider the authorisation procedure as time consuming and involving a high administrative burden, which leads to relatively high costs. The procedure is also considered unpredictable in some cases. This may deter companies from investing in innovation. The different opinions of competent authorities on whether a marketing authorisation can be granted, or on the details of the marketing authorisation, also create a barrier to the free movement of veterinary products within the Community.

#### 4.2.3 Options to address this issue

The authorisation system could be amended in order to achieve a genuine internal market for veterinary medicinal products. A more centralised risk assessment and authorisation procedure could streamline and increase efficiency and predictability, and speed up decision making. The resources gained could be invested in improving the quality of the system.

More or less centralised systems of authorisation and levels of co-operation will be assessed in the assessment:

- The first option is an optimal use of the current authorisation procedures for veterinary medicinal products at national and Community level (option 1: best use of current procedures). Competent authorities could put in place a system of enhanced co-operation with the aim of pooling the existing resources better at EU level, for example by points of excellence, pooling the best available expertise in the EU, assessing and/or authorising products for several Member States (assessment and authorisation of the application could be carried out by different bodies). Given that this option would make use of current authorisation procedures, each concerned Member State would have to give prior confirmation of its agreement to participate in this procedure.
- Each authorisation of a veterinary medicinal product, regardless of the procedure under which the medicine has been authorised and regardless of the authority involved, will be valid throughout the EU (option 2: each authority decides for all). This could apply to all products authorised after a specified date.
- Some Member States can decide to work together more and, by giving up the possibility to object to a decision, to automatically recognise a decision of another Member State (option 3: voluntary automatic recognition). The decision of the competent authority of one Member State will be valid and binding on the territory of the Member State(s) that co-operate within this structure.
- One body in the EU will authorize all types of veterinary medicinal products in the EU by means of a single authorisation procedure. The outcome would be binding on all Member States (option 4: centralised system); in this option a specific body would assess all future applications starting from a specified date.

The options are not mutually exclusive, as some of their features could be combined to create a new option. DG Health and Consumers is aware that the options provisionally selected take account of a limited series of factors and that they do not exhaust the full range of political choices that could be offered to the Commission. However, DG Health and Consumers takes the view that the three options selected represent the main political choices. Stakeholders are invited not only to evaluate the options, but also to enrich them and help to assess their feasibility and possible impact. In their replies stakeholders could refer to the effects of the option concerning efficiency, effectiveness, predictability, administrative burden and time-to-approval.

How do you rank your satisfaction with the current authorisation procedures? (optional)

- No opinion
- Very dissatisfied
- Dissatisfied
- Satisfied
- Very satisfied

How do you rank your satisfaction with the current centralised procedure? (optional)

- No opinion
- Very dissatisfied
- Dissatisfied
- Satisfied
- Very satisfied

How do you rank your satisfaction with the current decentralised and mutual recognition procedure? (optional)

- No opinion
- Very dissatisfied
- Dissatisfied
- Satisfied
- Very satisfied

What are your criteria for selecting the reference Member State in the decentralised procedure? (optional)

- Previous favourable experience
- Reputation for efficiency
- Reputation for scientific expertise



- Reputation for communication
- Geographical location
- Other

What are in your opinion the advantages, strengths, flaws and weakness of the current range of procedures for the authorisation of veterinary medicines? (optional)



Would you favour extending the scope of the Community procedure (extending the type of products that could be authorised by the Community procedure)? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Do you think a conditional authorisation, similar to the one included in the legal framework for human medicines, would help to mitigate the availability problem? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Do you consider that there is a need for several authorisation procedures in the EU? (optional)

- Yes
- No
- Don't know

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Do you consider it necessary that the number of authorisation procedures should be simplified by reducing it to only one? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Which of the above options described in paragraph 4.2.3 would you prefer? Would you prefer another option? Please explain your choice and try to specify in particular which economic, social and environmental effects you expect from your choice, giving as much as possible quantitative information as possible. (optional)

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What, in your experience, are the necessary conditions for a successful authorisation procedure, and what are the main obstacles? (optional)

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What could be done to improve the current authorisation procedures? (optional)

Do you consider that there are parts in the authorisation procedures in particular burdensome for SMEs? (optional)

- Yes
- No
- Do not know

Would you favour including in the legal framework a requirement to perform a risk-benefit assessment which also takes into account indirect risks related to the use of the veterinary medicine, for example the development of antimicrobial resistance? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

The first marketing authorisation is valid for five years (Article 28 of Directive 2001/82/EC.) and the authorisation may be renewed on the basis of a re-evaluation. Do you consider this system of renewal appropriate if an effective pharmacovigilance system and variations system existed for veterinary medicinal products? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Would you favour including in the legal framework a clear basis for restricting a marketing application and/or providing certain indications in cases where authorisation of the specific veterinary medicine would pose an indirect risk to animal or human health? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Would you favour that the legal framework provides a specific legal basis to restrict the use of antimicrobials which are critical for human medicine? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

## 4.3 Key issue N° 3: Packaging and labelling

### 4.3.1 The issue

Packaging and labelling requirements provide information to users and improve consumer protection. However, the costs to meet the requirements, particularly in terms of additional national requirements, may lead to a reduction in the range of products authorised for species and indications in smaller markets. Stakeholders take the view that the necessary costs to develop national packaging and labelling constitute a substantial obstacle to the development of products.

### 4.3.2 Consequences

There appears to be considerable scope for reducing the administrative burden related to packaging and labelling and thereby contributing to the objectives of this review.

### 4.3.3 Options to address this issue

One possible option could be to consider packaging and labelling requirements as being the responsibility of the marketing authorisation holder. Also the potential to simplify the requirements could be assessed, for example by taking the view that language requirements are the responsibility of the Member States, who would therefore decide on the languages to be used

in their country. Finally, the quantity of compulsory key information could be reduced by optimal use of abbreviations, pictograms and leaflets<sup>16</sup> and references to information available on line.

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16. Information that would not fit on the immediate label and outer carton could be put in the leaflet; pictograms could clarify text instructions and provide a way to reduce or to replace text in multilingual labels.

Do you consider EU - packaging and labelling requirements essential in terms of providing appropriate information to the users of veterinary medicines? (optional)

- Not essential at all
- Not essential
- Somewhat essential
- Clearly essential
- Very much essential
- Don't know

Would you be in favour of fewer packaging and labelling requirements, or none at all, in the EU legal framework? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Would you favour Member States being allowed to decide which language is to be used for labelling and packaging? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Can you agree to have specific requirements for small packs (small packaging would include ampoules, blister packs and other immediate packs of relative small size), e.g. information being given on the outer packaging of small packs? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Would you be in favour of reducing the information on the label as much as possible and to making it easier for labels to be used in a number of Member States? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Do you have any concrete proposals to amend the legal framework? (optional)



## 4.4 Key issue N° 4: Pharmacovigilance and monitoring

### 4.4.1 The issue

Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. The existing legal framework for veterinary pharmacovigilance mirrors human pharmacovigilance. This has led to equally complex requirements in both veterinary and human pharmacovigilance. Stakeholders generally consider that veterinary pharmacovigilance is too heavy and burdensome. They point out that, when the current requirements were established, it was assumed that the needs for human patients applied equally to veterinary medicines and, consequently, no specific consideration was given to the actual needs and expectations of veterinarians and animal owners. However, it is important to stress that stakeholders do not question the need for adequate surveillance. Furthermore, stakeholders report a lack of harmony in the implementation of the EU legal framework for pharmacovigilance in Member States.

At the moment no monitoring system exists that delivers standardized and reliable data on usage of antimicrobials in food-producing species and companion animals in the EU.

#### 4.4.2 Consequences

Pharmacovigilance that is too heavy and burdensome is just as damaging as an unnecessary administrative burden.

No comparable and reliable data are available on usage of antimicrobials in food-producing species and companion animals in the EU. Reliable data would provide a tool for risk profiling, risk-benefit analysis and to assess the impact of measures taken in relation to the prudent use of antimicrobials.

#### 4.4.3 Options to address this issue

There appears to be to considerable scope for reducing the administrative burden related to veterinary pharmacovigilance. The question is how to simplify the pharmacovigilance without compromising adequate surveillance. For this it seems required that the fundamental principles and needs underlying the requirements for conducting veterinary pharmacovigilance must be reconsidered. At the end of 2008 the Commission submitted proposals for legislation on pharmacovigilance<sup>17</sup>. Their aim is to strengthen and rationalize the EU pharmacovigilance system for human medicinal products but they do not cover the veterinary sector. Aspects of these Commission proposals could be used to improve the veterinary pharmacovigilance system.

However, first of all it appears necessary to evaluate whether the needs and expectations relating to the safety of veterinary medicines should differ from those of human medicines, and - if so - how this should be reflected in the veterinary pharmacovigilance rules. Two specific aspects of the Commission proposal in relation to pharmacovigilance for human medicines are highlighted.

Directive 2001/82/EC requires that a detailed description of the pharmacovigilance system is provided in the marketing authorisation dossier. By introducing the concept of a "pharmacovigilance master file" it would be possible to avoid the duplication of much of the information that is common to all products from the same company, because it would allow the applicant to provide the common information of the pharmacovigilance dossier once only.

A decision could be taken to limit reporting to serious adverse reactions and also to restrict the submission of Periodic Safety Update Reports (PSURs) to serious situations (and to abolish the periodic submission of PSURs).

A general legal base could be introduced in the legal framework to enable EU harmonised systems for data collection on the sales and uses of veterinary medicinal products to be set up in the Member States.

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17. See [http://ec.europa.eu/enterprise/sectors/pharmaceuticals/human-use/pharmacovigilance/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/pharmaceuticals/human-use/pharmacovigilance/index_en.htm) for further details.

Do you consider that the needs and expectations concerning the safety level of veterinary pharmacovigilance could be different for human pharmacovigilance? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

If so, please substantiate your reply. (optional)

Which measures would you like to propose to amend veterinary pharmacovigilance? (optional)

Would you favour the introduction of a masterfile for pharmacovigilance or any other means of reducing the regulatory burden of authorisation holders? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Do you think that there are particular problems in the legislation for pharmacovigilance for SMEs? (optional)

- Yes
- No
- Do not know

Would you favour the introduction of a specific legal base for establishing harmonised systems for data collection on the sales and use of medicines in the EU? (optional)

- Favour not at all



- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

## 4.5 Key issue N° 5: The distribution channel

### 4.5.1 The issue

Member States made use of the latitude for national implementation in the legal framework with regard to the veterinary pharmaceutical supply chain. This resulted in divergent requirements for operators in Europe. Some stakeholders indicate that, in order to build a genuine single market for veterinary medicinal products, it is not sufficient to harmonise the authorisation of veterinary medicines. The conditions for companies and practitioners to operate in the whole pharmaceutical supply chain (manufacturers, importers, wholesalers, distributors, retailers, veterinarians and farmers) should also be standardised and harmonised in the EU as well. For example, different rules exist in Member States for the prescription of veterinary medicines. This leads to different standards as regards the use of medicines. In the context of the control of residues in food of animal origin the way in which veterinary medicines are being used is an important issue. According to some stakeholders the legal framework should also be updated to include new methods of distribution such as electronic prescription, internet trade, internet pharmacies and mail order selling. It is also questioned whether the current legal framework is properly designed to respond to the situation of parallel imports<sup>18</sup>.

Counterfeit<sup>19</sup> medicines may present a threat to animal health through lack of therapeutic effect and/or through inherent toxicity. The most harmful consequences of counterfeit veterinary medicinal products on human health could be the non-respect of maximum residue limits of veterinary substances in foodstuffs and the occurrence of toxic materials in the counterfeit medicines in foodstuffs. The discovery of counterfeit medicines damages also the image of industry that complies with the rules. At EU level no specific rules exist on counterfeiting of veterinary medicinal products. In 2008 the Commission adopted a proposal to amend Directive 2001/83/EC for medicinal products for human use as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source<sup>20</sup>, which foresees specific measures to address the increased risk in the legal supply chain.

### 4.5.2 Consequences

Stakeholders indicate that a genuine single market for veterinary medicinal products will not develop as long the conditions for companies to operate in the pharmaceutical supply chain of veterinary medicines would not be better standardised and better harmonised. For example, Article 70 of Directive 2001/82/EC allows veterinarians to provide services in another Member State on a very restrictive basis. However, these cross-border veterinarian activities are regulated both by divergent rules of the Member State in which his veterinarian practice is situated and the host Member State in which he is active at that moment, resulting in a complex and unclear legal environment.

Counterfeiting is difficult to detect, to investigate and to quantify. No specific statistics exist on the level of counterfeit veterinary products on the European market. Therefore it is unknown whether counterfeiting provides a real risk for animal or public health. What is known is that counterfeiting of medicines occurs worldwide and the problem is not confined to human medicines as also instances of counterfeited veterinary medicinal products are recorded in Europe, China and the U.S.A.

Parallel trading could encourage trade and help strengthen competition. However, the current legal situation for parallel trade may affect the whole EU authorisation system as it provides a way, in addition to the relevant authorisation procedures, of placing a product on the market that is less expensive for companies. Some interested parties question whether the parallel trade system provides sufficient guarantees on the quality, efficacy and safety of the medicine than the

planned authorisation procedures and they point out that parallel trade can result in a less effective pharmacovigilance system.

#### 4.5.3 Options to address this issue

The legal framework could help to standardise the requirements for operators in the distribution chain. For example, harmonisation to the full extent of the prescription status could improve the functioning of the EU system of food control and at the same time contribute to the realisation of a common market in veterinary medicines. Also cross-border activities of veterinarian practitioners could be facilitated compared to the current system laid down in Article 70 of the Directive 2001/82/EC. Regulators, companies and consumers should have confidence in the effective functioning of the veterinary supply chain in Europe. The comprehensive approach for veterinary medicines of the EU, including a risk-based inspection system, should also better tie in with the European rules for foodstuffs and feed.

18. Parallel import is the practice of importing into and then the marketing in one Member State from another and it allows distributors to capitalise on price differences between Member States. It is accepted by the European Court of Justice as a way to market pharmaceutical products in EU. A parallel-import marketing authorisation is needed to be able to market a parallel-imported product (this does not apply to products with a Community Marketing Authorisation).

19. According to the World Health Organisation, a counterfeit medicine is "a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source". Counterfeiting includes medicines with wrong ingredients, incorrect quantities of active ingredients, and/or products with fake packaging. It can apply to both branded and generic products.

20. SEC(2008)2674

Do you consider that there is a need to standardise and harmonise the conditions for operators in the EU distribution channel (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

If so, would you favour standardisation by amending the European legal framework? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Would you be in favour of the prescription of medicines being standardised in the EU? (optional)

- Favour not at all

- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Do you consider that cross-border activities, for example involving veterinarians active in two Member States, are hampered by the current rules? (optional)

- Yes
- No
- Do not know

Do you agree that counterfeit medicines have penetrated the veterinary supply chain? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

If so, do you consider that there are risks to public health from the penetration of counterfeit medicines into the veterinary supply chain? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Should the issues of internet trade, mail order selling or parallel import be addressed in the revision of the legal framework for veterinary medicines? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Do you consider that the legal framework should be supplemented with specific requirements on internet trade, mail order selling or parallel import? (optional)

- Yes
- No
- Do not know

If so, do you have any proposals? (optional)

Do you consider counterfeiting of veterinary medicinal products to be a problem for animal health and/or public health EU? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

If so, what do you consider to be the most important stages where counterfeit veterinary medicinal products enter the production and distribution chain of veterinary medicinal products or human medicines? (optional)

Do you have qualitative or quantitative data on counterfeit veterinary medicinal products? (optional)

- Yes
- No

Do you think that legislative measures are necessary to tackle counterfeit veterinary medicinal products? (optional)

- Yes
- No
- Do not know

## 4.6 Key issue N° 6: The use of drugs not in accordance with the summary of the product characteristics (off-label use)

### 4.6.1 The issue

According to Articles 10 and 11 of Directive 2001/82/EC Member States shall ensure that, where there is no authorised veterinary medicinal product in a Member State for a condition affecting an animal species, measures exist that would allow a veterinarian, by way of exception, and where it is necessary in order to avoid unacceptable suffering of the animal, to use medicines off-label within strict limits (this procedure is called "cascade"). These limits include the restriction that the medicine must be administered by the veterinarian or given under his/her personal responsibility and that the veterinarian specifies an appropriate withdrawal period. The veterinarian shall also keep adequate records of the off-label use. For food-producing species, the legal framework specifies the minimum period necessary between the last administration of veterinary medicinal product to animals and the production of foodstuffs from such animals for off-label use ("a minimum withdrawal period")<sup>23</sup>. This withdrawal period is standard for all types of foodstuffs. Off-label use - which is an exception to the principle that authorised veterinary medicines have to be used to treat animals for a specific disease - seems to be applied very frequently in Europe. Moreover, the conditions for the application of Articles 10 and 11 in the Member States also appear to differ in the EU. The question is whether the current off-label use could be simplified and whether it should be adapted in order to lower the risks for human and animal health.

The current legal framework does not contain a basis to restrict the off-label use of antimicrobials which are critical in human medicine or where their use would constitute an indirect risk to public health.

### 4.6.2 Consequences

There are not enough authorised medicinal products available to treat diseases occurring in animals, particularly in the case of minor species. Due to this deficiency, the off-label use of products is a frequent occurrence. The extent to which and the manner in which the "cascade" has been implemented across the EU also differs and has therefore led to disharmony on EU market for the use of veterinary medicines.

As stated earlier Directive 2001/82/EC allows a veterinarian to use a product that is authorised in another Member State where there is none available in the veterinarians Member State. However, this has led, in some cases, to a situation where products for which an authorisation in a Member State has not been accepted, are being used there legally by the "cascade".

The current legal framework does not provide for the possibility of excluding certain antimicrobials for off-label use which are critical in human medicines. Therefore it is the responsibility of the veterinarian to ensure that off-label use is applied in an appropriate way, also taking into consideration the potential risks it may create for public and animal health. For some food species, stakeholders consider the specified minimum withdrawal periods to be too long in relation to the (economical) life expectancy of the treated animals. Moreover, for pharmacologically active substances for which the scientific committee concluded that it is not necessary to establish a maximum residue limit in order to protect human health (see Article 14 of Regulation (EC) No 470/2009), the minimum withdrawal periods also apply where the cascade is used".

#### 4.6.3 Options to address this issue

The legal framework could be amended in order to have a clarified and simplified legal framework for the treatment of animals in the absence of authorised medicinal products.

For off-label use a withdrawal period could be introduced that is more closely geared to the type of foodstuff, animal species and medicinal product.

23. See Article 11(2) of Directive 2001/82/EC

Is the above an accurate description of the situation? (optional)

- Yes
- No

What is your appraisal of the situation? (optional)

Do you consider that off-label use of medicines is too common in the EU? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Please substantiate your reply (optional)

Do you have quantitative or qualitative data on off-label use? (optional)

- Yes
- No

If so, please provide. (optional)

Are you aware of different national procedures or interpretations of the legal framework? (optional)

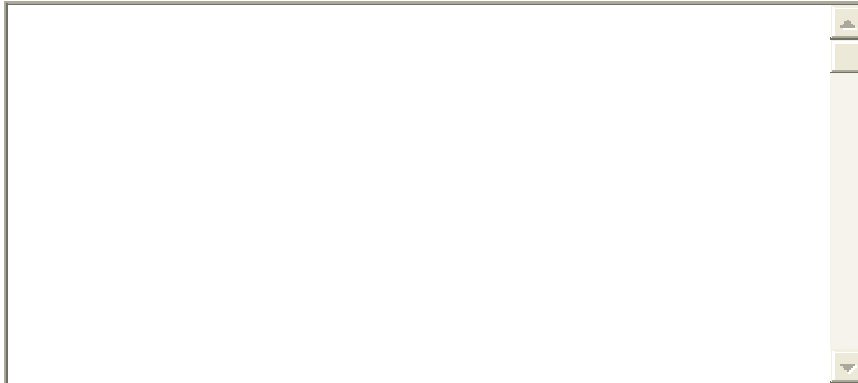
Do you consider the off-label use a potential hazard for animal and /or public health? (optional)

- Yes
- No
- Do not know

Would you consider it appropriate to exclude certain medicines from off-label use? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Please give reasons for your answer. (optional)



Would you favour more or less restrictive conditions for off-label use in order to increase the availability of veterinary medicinal products? (optional)

- Favour not at all
- Favour not
- Favour somewhat
- Favour clearly
- Favour very much
- Do not know

Do you have concrete proposals (to amend the legal framework) concerning off-label use? (optional)





## 4.7 Key issue N° 7: Harmonisation of already authorised veterinary products

### 4.7.1 The issue

Once a marketing authorisation has been granted, new requirements may be implemented by means of amendments to the legal framework. Therefore, over time, marketing authorisations for the same product may differ from one Member State to another. Also, the competent authorities of the Member States may have adopted divergent decisions for the same product under the same rules. Directive 2001/82/EC provides a mechanism, the so-called referral procedure, to promote the harmonisation of veterinary medicinal products that are authorised in the Community. This referral culminates in a scientific opinion from the Committee for Medicinal Products for Veterinary Use (CVMP) which the Commission will use as a basis to draft a single decision. Member States are required to either grant, maintain, suspend, or withdraw the marketing authorisation, or vary the terms of authorisation as necessary to comply with the Commission decision. Stakeholders have indicated that the referral procedure has not led to sufficient harmonisation of the veterinary medicinal products market in the Community.

### 4.7.2 Consequences

Marketing authorisations may exist with different conditions in the EU for the same veterinary product. This may lead to a public health concern and/or an animal health concern; it may complicate the functioning of authorisation procedures and may impose an additional administrative burden on enterprises. Since referral procedures demand of the CVMP a substantial part of its available capacity, this will impact on the Committee's other essential activities. Harmonization presents a risk in terms of availability, as the data relating to old products may not be sufficient according to current standards. In most cases it is not economically feasible for pharmaceutical companies to conduct additional studies to update the dossier and, as a result, products disappear. Over the short term harmonisation means an increase in additional administrative burden. This should be weighed against the reduced additional burden for marketing authorisation holders in the future.

### 4.7.3 Options to address this issue

A voluntary or compulsory procedure could be developed to harmonise veterinary medicinal products that are already authorised in the Community. It is noted that old products have been assessed and authorised in the past, and there is experience of the use of these veterinary medicinal products and periodic safety reports were submitted. It has to be discussed whether "old products" should be assessed on the current data requirements. Another option could be to have free circulation of the already authorised products in the EU if there is no evidence of any negative effects of these medicines.

Do you agree with the description of the issue? (optional)

Yes

No

Do you consider it necessary to update and to harmonise already authorised medicines? (optional)

No opinion

Strongly disagree

Agree

Strongly agree

Please explain your position, and try to specify it in particular with type of data should be requested for this update of already authorised medicines. (optional)

If a procedure were established to update and to harmonise already authorised medicines, would you consider it appropriate to apply the procedure differently according to the public health risks involved or to other criteria (e.g. to prioritize the harmonisation of products with high public health concern)? (optional)

- Yes
- No

Please substantiate your position. (optional)

If a procedure were established to update and to harmonise already authorised medicines, would you prefer a compulsory approach? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

## 4.8 Key issue N° 8: New needs and new challenges

### 4.8.1 The issue

There are many serious animal diseases on the borders of the EU. A rise in the level of international trade and travel has increased the threat from previously unknown diseases in Europe. Climate change may further enhance the probability of accidental introduction of diseases in the EU. There is also the possibility that vectors of diseases will move into new habitats and spread beyond their existing areas. Therefore new animal health challenges have

emerged and will continue to emerge. Last decades the emergence of for example Bovine Spongiform Encephalopathy (BSE), Foot and Mouth disease (FMD) and Classical Swine Fever has reminded us of the economic and social impacts animal diseases can have. Effective disease control requires a fast and effective response to a disease outbreak and alternative approaches which can supplement existing methods are needed. The current legal framework already provides some tools to respond to new needs and challenges. Pursuant to Article 7 of Directive 2001/82/EC a Member State may authorise the marketing or administration to animals of veterinary medicinal products which have been authorised by another Member State. Article 8 of Directive 2001/82/EC provides the possibility, in the event of serious epizootic diseases, to allow the use of immunological veterinary medicinal products without a marketing authorisation in the absence of a suitable medicinal product. Whilst authorisation at EU level against transboundary diseases is the preferred option, experience has shown that in the event of disease emergencies Member States have made use of the legal provisions to allow use of products at national level. Authorisation of products at EU-level has been much slower, which has often led to the veterinary medicines being authorised too late to be of widespread use.

New technologies, therapies and medicines for animals are emerging. They offer new opportunities for treating or preventing animal diseases. Some of these new developments may be complex and have a new technical specificity, and therefore lie at the border of being a veterinary medicinal products or another type of product (e.g. medical devices). The current veterinary legal framework does not have specific provisions for advanced therapies as is the case in human medicines.

The issue is whether the legal framework can respond appropriately to new needs and new challenges.

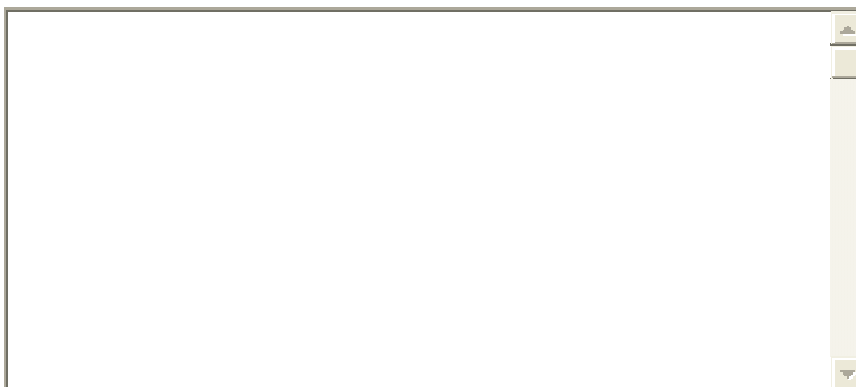
#### 4.8.2 Consequences

If the legal framework is not properly designed to respond effectively to new veterinary needs and challenges, this would pose significant problems in term of ensuring a fast and effective response to outbreaks of new diseases. In order to exploit the results of research, and to support its development, the regulatory requirements and environment should evolve in parallel with advances in technology.

#### 4.8.3 Options to address this issue

The legal framework and environment could be better designed to respond effectively to new veterinary needs, new circumstances and new technologies. However, it is unclear whether there is a real need to change the legal framework.

Can you specify the new veterinary needs and challenges to which the legal framework may have difficulties in responding effectively? (optional)



Do you agree that there are difficulties in the assessment of medicines developed or produced by new technologies? (optional)

- No opinion
- Strongly disagree

- Agree
- Strongly agree

Should this issue of new needs and new challenges be addressed in the review? (optional)

- No opinion
- Strongly disagree
- Agree
- Strongly agree

Do you have proposals how the need to authorise veterinary medicinal products urgently in the event of an emergency can be better balanced against the need for an appropriate benefit-risk assessment of the use of these products (for which companies have to provide extensive data)? (optional)

Do you have concrete proposals (to amend the legal framework) in relation to new needs and challenges? (optional)

## 5. General information on submitting parties

Please give name, telephone number, e-mail address, Member State / country (optional)



Please indicate to what category you belong as submitting party: (compulsory)

- Citizen
- Non-business organisation
- Business organisation / enterprise
- A public authority
  
- Farmer
- Veterinarian
- Manufacturer
- Wholesaler
- Pharmaceutical industry
- Importer
- Researcher
- Other

We thank you for your kind co-operation.



## Annex 2

### Responding organisations and individuals in alphabetical order

Dr Hans-Jürgen Abmayr	Enterprise
ADS ACUIVAL — Agrupacion de Defensa Sanitaria Acuicultura de la Comunitat Valenciana	Non-business organisation
ADSG — Galician Association of Trout Farms	Non-business organisation
AEMPS — Agencia Espanola de Medicamentos y Productos Sanitarios Directora	Public authority
Agence Nationale du Médicament Vétérinaire, Agence Nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail, Ministère de la Santé et des Sports, Ministère de l'Alimentation, de l'Agriculture et de la Pêche, France	Public authority
AVEC — Association of European Poultry Processors; EPB — European Poultry Breeders; AEH — Association of European Hatcheries	Enterprise
Chiara Agnoli	Enterprise
Dr Peter Aigner	Enterprise
AHDA — Animal Health Distributors Association	Non-business organisation
Alpharma Animal Health	Enterprise
Andermatt Biovet	Enterprise
Animal and Plant Health Association	Enterprise
ANMVI — Italian National Association of Veterinarians	Non-business organisation
Ann Williams	Enterprise
Associazione Piscicoltori Italiani	Non-business organisation
Brendan Barnes	Citizen
Franz Barth	Enterprise
Burkard Barthel	Enterprise
Bayer Animal Health	Enterprise
Bayerische Staatsministerium für Umwelt und Gesundheit	Public authority
Kirstin Becker	Enterprise
Dr Christian Blaschke	Citizen
Borion	Enterprise
Jean Bouchet	Enterprise
British Trout Association	Non-business organisation
Boehringer Ingelheim Animal Health	Enterprise
Bundesverband für Tiergesundheit	Enterprise
Bundestierärztekammer	Non-business organisation
Bundesverband Praktizierender Tierärzte	Non-business organisation

Camilla Cammelli	Enterprise
CEVA Santé Animale	Enterprise
Coophavet	Enterprise
CVMP — Committee for Medicinal Products for Veterinary Use	Public authority
European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe	Non-business organisation
Danish Medicines Agency	Public authority
Dr Elke Deus	Citizen
Department of Agriculture, Fisheries and Food, Ireland	Public authority
Barbara Dihlmann	Enterprise
Dociu	Enterprise
ECEAE — European Coalition to End Animal Experiments	Non-business organisation
ECVH — European Coalition on Veterinary Homeopathy	Non-business organisation
Elanco Animal Health	Enterprise
EGGVP — European Group for Generic Veterinary Products	Enterprise
Dr Susanne Elsner	Enterprise
Dr Reinhold Erbing	Citizen
Eurovet Animal Health	Enterprise
Andrea Fabris	Citizen
FAMHP — Federal Agency for Medicines and Health Products, Belgium	Public authority
FEADSA — Federacion Espanola de Agrupaciones de Defensa Sanitaria de Acuicultura	Non-business organisation
FEAP — Federation of European Aquaculture Producers	Business organisation
Federal Ministry of Food, Agriculture and Consumer Protection; Federal Ministry of Health, Germany	Public authority
FEEDM — Fédération Européenne des Emballeurs et Distributeurs de Miel Grosse	Non-business organisation
FFA — Fédération Française d'Aquaculture	Enterprise
FIDIN — Fabrikanten en Importeurs van Diergeneesmiddelen in Nederland	Enterprise
FNOVI — Federazione Nazionale degli Ordini dei veterinari Italiani	Public authority
Gianluca Fortino	Enterprise
Mirella Fossaluzza	Enterprise
FVE — Federation of Veterinarians of Europe, Belgium	Non-business organisation
FVE — Federation of Veterinarians of Europe, Germany	Non-business organisation
Dr Stefan Gabriele	Citizen
Dr Volker Gerlitzki	Citizen
German Federal Environment Agency	Public authority
Michaela Gambs	Citizen
Bettina Graefenstedt	Enterprise



Dr Frank Hildenbrand	Enterprise
IMB — Irish Medicines Board	Public authority
Icelandic Medicines Agency	Public authority
Ittica Tranquilli	Enterprise
Regierungspräsidium Tübingen	Public authority
Roberto Giavenni	Enterprise
IFAH-Europe — International Federation of Animal Health	Enterprise
Christophe Hugnet	Citizen
Janssen Animal Health	Enterprise
Dr Peter Kellner	Enterprise
Dr Silke Knoll	Enterprise
Dr Thomas Knacker	Enterprise
Dr Heidi Kübler	Non-business organsiation
Dott. Vet. Beate Kuhl	Citizen
Laboratorios Ovejero	Enterprise
Dr Stephan Lübke	Citizen
Holger Maschke	Citizen
Matthias Link	Citizen
MedicAnimal	Enterprise
Medical Prducts Agency, Sweden	Public authority
Merial, Belgium	Enterprise
Merial, France	Enterprise
Marian Mestdagh	Enterprise
Ministerium für Umwelt und Naturschutz, Landwirtschaft und Verbraucherschutz des Landes Nordrhein-Westfalen	Public authority
Ministerium für Ländlichen Raum, Ernährung und Verbraucherschutz, Allgemeine Veterinärangelegenheiten, Germany	Public authority
Ministero della Slute Direzione Generale Sanita Animale e Farmaco Veterinario	Public authority
Ministry of Agriculture, Environment and Consumer Protection, Germany	Public authority
Ministry of Agriculture and Forestry, Finland	Public authority
Ministry of Agriculture, Nature and Food Quality, Department of Food, Animal Health and Welfare and Consumer Policy, The Netherlands	Public authority
Ministry of Environment, Health and Consumer Protection, Department for Consumer Protection, State of Brandenburg	Public authority
Ulrich Möhnle	Enterprise
National Office of Animal Health, UK	Enterprise
National Organisation for Medicines, Greece	Public authority
Niedersächsisches Landesamt für Verbracherschutz und Lebensmittelsicherheit	Public authority
Dr Jo-Ann Lawrence	Enterprise
Dr Ines Ott	Enterprise

Novartis Animal Health	Enterprise
PAN Germany –Pesticide Action Network Germany	Non-business organisation
PEI — Paul Ehrlich Institut	Public Authority
PETA — People for the Ethical Treatment of Animals	Non-business organization
Georg Petry	Enterprise
sPfizer Animal Health, UK	Enterprise
PGEU — Pharmaceutical Group of the European Union	Non-business organisation
sPfizer, Italy	Enterprise
Stephan Plank	Citizen
Paky Prenota	Citizen
Annegret Rehrmann	Non-business organisation
Dr Ulrike Quante	Enterprise
Dr Gerd Ricker	Citizen
Richter Pharma	Enterprise
Dr Ulli Rösel	Enterprise
Royal College of Veterinary Surgeons	Public authority
Pier Antonia Salvador	Enterprise
Sebastian Scala	Enterprise
Christoph Schäuble	Citizen
Dr Waltraude Scheffel	Public authority
Julia Scholl	Citizen
Dr Bernd Schulze	Enterprise
Scottish Salmon Producers' Organisation	Enterprise
SIMV	Enterprise
Slovenia	Public Authority
Dr Petra Sindern Seevering	Enterprise
SME Ireland	Enterprise
SNVEL –Syndicat National des Vétérinaires d'Exercice Libéral	Business organisation
SNVECO	Business organisation
Société Nationale des Groupements Techniques Vétérinaires, France	Non-business organisation
Dr Mary-Anne Sommer	Enterprise
Dr Martina Spangenberg	Enterprise
Are Thoresen	Enterprise
Tierärztliche Gemeinschaftspraxis WEK Lohe	Enterprise
TVM	Enterprise
Veterinary Council of Ireland	Public authority
VIRBAC SA	Enterprise
VMD — Veterinary Medicines Directorate	Public authority
Rupert Weber	Enterprise
Kai Boris Wiese	Enterprise
Dr Ulrike Zeyen-Blumrich	Citizen

