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POSITION PAPER REGARDING AVAILABILITY OF PRODUCTS FOR MINOR USES AND MINOR SPECIES (MUMS)

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POSITION PAPER REGARDING AVAILABILITY OF PRODUCTS FOR MINOR USES AND MINOR SPECIES (MUMS)[1]

1. PURPOSE AND BACKGROUND OF THE DOCUMENT

For some time there has been considerable concern amongst all parties concerned with animal health in the EU especially the veterinary profession, about the lack of veterinary medicines for minor uses, and for minor species. The EMEA at the behest of its Management Board began its discussions and consultations on this increasing problem in 1998. Following the European consultation conference on this important topic hosted by the Commission in Brussels in July 1999, the EMEA created a task force to consider the findings of the conference and to make a number of recommendations, which were one of the sources considered in the Communication from the Commission to the Council and the European Parliament on the availability of veterinary medicinal products COM(2000)806 final – 5 December 2000. The availability problem is not unique to the EU: in the USA a proposal on legislation on drug approval for minor species and minor uses, as defined in the USA, had been proposed in 1999 and the Minor Use and Minor Species Animal Health Act of 2003 recently passed the US Congress.

Subsequently the CVMP has reflected on this problem of lack of medicines and communicated its concerns and proposals on several occasions in various documents and communiqués. In addition, the EMEA has prepared a proposal for the Commission on a policy analogous to "orphan drugs for human use" for veterinary medicines by means of a specific legal instrument, which was endorsed by the Management Board of EMEA.

It becomes clear that the problem is, in large part due to the costs of research and development being a disincentive to industry to bring such new products to the market place when the return on investment is likely to be small and certainly less than that resulting for mainstream products for major species. One major cause of the lack of authorised veterinary medicinal products seems to be also the limited economic value of most farmed animals and the fact that the farmer has to bear the total cost of any treatment. Furthermore, the markets are much weaker and more fragmented than that of human health care.

In food producing animals a major problem has been the difficulties to establish maximum residue limits (MRLs) for so-called "old" products prior to the 1 January 2000 deadline laid down in Community law, Council Regulation (EEC) 2377/90. Despite the best efforts of the CVMP some medicines without alternatives for treatment in commercial veterinary practice have been lost due to insufficient data being provided by the sponsor companies to set MRLs, particularly in respect to the use in minor species. For other indispensable substances no company sponsored the compilation of a dossier for the establishment of MRLs. In addition there is shortfall of immunological products in the food animal sector partly as the testing requirements in Community law are seen as onerous and economically non-viable for such products in niche markets. Existing products are furthermore being withdrawn from the market where market size does not justify the investment necessary to upgrade dossiers to current regulatory requirements not least in an industry going through considerable rationalisation and consolidation. The problem is apparent in the companion animal sector as well.

Regarding food-producing animals there is a particular concern that in the absence of MRLs and authorised medicinal products other medicinal products or chemical substances could be illegally used

[1] **Minor use** is defined as a minor indication in a major species.
Minor species is defined by threshold of animal numbers in the EU. In some cases other factors than animal numbers have been used to define specified animal species as minor. These include, for instance, low economic value of the single animal (e.g. honey bee).

without a possibility to efficiently control maximum residue limits and ensure consumer safety through appropriate withdrawal periods.

The Commission, in its communication to the Council and the European Parliament of 05.12.2000, made recommendations to overcome the lack of medicines: As short term goal the adaptation of the scientific requirements for establishing MRLs and proposed that the CVMP would develop guidance for the extrapolation of existing MRLs to further species and guidelines on efficacy testing for veterinary medicines used in limited market segments and species. For the medium term the Commission considered adapting the law with the main objectives to provide more incentive to industry to develop products for certain market segments and permit and facilitate use of medicines authorised in other EU Member States. Also reflections on possibilities of developing a policy analogous to the "orphan drugs for human use" for veterinary medicinal products by means of a legal instrument would continue.

In recent years there has been considerable effort by the CVMP focussing on extrapolation of existing MRLs to further species and this is addressed in detail below. Despite these efforts the availability problem is still prevalent and now the EMEA and CVMP, as well as the EU Member States, industry and the Federation of Veterinarians of Europe have called for further action. The CVMP and its Efficacy Working Party (EWP) developed the document called Points to Consider Regarding Availability of Products for Minor Species and Minor Indications addressing general policy issues on minor uses and minor species including definitions of minor species and minor uses for public consultation in February 2002 (EMEA/CVMP/610/01-Consultation). The Committee having reviewed the comments received during that consultation period considered that a more strategic broader approach was needed and after further reflection on what progress could be made and as a result has developed this Position Paper on the Availability issue as a whole. The Position Paper has now been finalised based on the new additional comments received during the consultation period in 2003.

Since the publication of the Position Paper for consultation in June 2003 the review of the pharmaceuticals legislation has been finalised resulting in new provisions or modifications aimed at overcoming the availability problem. In finalising the Position Paper these new provisions achieved through the co-decision procedure between the Commission, the European Parliament and the Council have been taken into account.

This paper considers the position today following the progress made since 1999-2000, and aims to define the problem in some depth and makes suggestions for possible solutions. In particular a more pragmatic approach is called for concerning the dossier requirements for minor uses in major species and minor species in general. This is intended to facilitate a consistent approach throughout the EU, whilst at the same time providing appropriate guidance to industry, which has interest with regard to local markets as well as the whole of the EU. Such proposals to selectively adapt data requirements would hopefully encourage industry to consider again developing these important products. Proposals for harmonised approaches within the EU to use the previous and the new provisions in the legislation are another element of the Position Paper. The proposals are characterised as short, medium and long-term goals. There should be no illusion about the challenges to be faced if such a strategy is to be achieved, as clarifications with regard to legal framework and proposals for further changes in EU law merit further consideration.

The goal of the CVMP is to establish the standards of quality, safety and efficacy for veterinary medicinal products for medicines intended for minor uses and minor species, for both pharmaceutical and immunological products. This will provide the industry with a degree of certainty for investing scarce resources for the development of medicines for minor uses and minor species. However, it is emphasised that no progress can be made unless the veterinary medicines industry actively commits to develop the needed products for minor uses or minor species and shows its intention to file applications for marketing authorisations. The Interested Parties to the CVMP during the process of consultation on this subject have also emphasised the need to stem the loss of existing products wherever possible, because once lost it is extremely difficult to reauthorise these products. In addition, any future initiatives should ensure a harmonised approach in the requirements set down by Member States for authorising such products in the mutual recognition procedure.

2. DEFINING THE PROBLEM

2.1. The legislative situation in the EU with regard to requirements for minor uses and minor species

No specific legislation exists in the EU for veterinary medicinal products for minor use and minor species. The recent review of the pharmaceutical legislation recognised the lack of medicines in certain areas and that increased data requirements have led to a gradual reduction in the range of authorised products for the species and indications representing smaller market sectors. Council and Parliament Directive 2004/28/EC amending Directive 2001/82/EC stresses the need to stimulate the interest of the veterinary pharmaceutical industry in certain market segments to encourage development of new veterinary medicinal products and introduced additional provisions in this respect and calls for improved harmonisation of procedures between Member States. The provisions in the legislation relevant for the authorisation and use of veterinary medicinal products for minor uses and rare species are outlined below.

Council Directive 2001/82/EC, Article 10, permits Member States in exceptional circumstances to allow off label use of veterinary medicinal products or the use of a human product by a veterinarian when an authorised veterinary medicinal product is not available (cascade principle). Although the application of this article is intended for exceptional situations where no suitable product is available, it is in fact used for all off label use, though the existing provisions are not consistently applied across the EU Member States. Although such off label use is permitted, these provisions in the Directive are not intended to compensate for insufficient availability. Member States have tolerated this to date, as there is no harmonised, specific procedure for authorising medicines for minor uses and minor species.

The recent amendments of Directive 2001/82/EC by Directive 2004/28/EC will extend and clarify the applicability of the cascade (Articles 10 and 11 of Directive 2004/28/EC). The main changes intended to increase availability are that the new provisions will allow the for use of veterinary medicinal products authorised in other Member States and that there are specific derogations for horses from the provisions for food-producing species. The new Directive also empowers Member States to take the necessary measures that the veterinarian can apply the cascade if there is no authorised medicine available for a specific condition, providing that for such procedural off label use the pharmacologically active substances in the products concerned must be included in Annex I, II or III of Regulation 2377/90.

Based on information gathered about procedures used in the Member States for licensing veterinary medicinal products for minor species and indications and considering the recent review of the legislation it has become evident that

- There are no clear and consistent definitions for minor species or minor uses
- There is no harmonised, specific and clearly defined procedure for authorising medicines for minor uses and minor species. Very few countries have a specific authorisation procedure in place and applications are mostly treated on a case-by-case basis.
- Member States use the cascade system to meet the need of using necessary but unauthorised drugs. It is hoped that the changes to the cascade in the amendment of Directive 2001/82 will facilitate a limited increase in product availability and allow a more consistent interpretation of this section of the legislation by all Member States. Efforts should be undertaken by all national authorities to harmonise their interpretation of this section of the amended legislation, particularly regarding the measures to be put in place to allow its application by the veterinarian.

Legal powers exist in both Regulation 2309/93 and Directive 2001/82/EC, and their revisions Regulation 726/2004 and Directive 2004/28/EC, for marketing authorisations in exceptional circumstances to be granted subject to a requirement for the applicant to introduce specific procedures thus such conditional authorisations may be granted for a limited duration with fewer requirements for part IV (efficacy) of the dossier. This allowance has not yet been used for centrally authorised veterinary products for minor uses/minor species and is applied, if at all, only in a rather heterogeneous manner in different Member States. The amendments of Directive 2001/82/EC and

Regulation 2309/93 by Directive 2004/28/EC and Regulation 726/2004, respectively, offer more specific options to address the non-availability in exceptional circumstances, and specify the conditions stressing that the specific obligations should address in particular the safety of the veterinary medicinal product. Agreement on a consistent approach to such exceptional marketing authorisations for the products for minor uses or minor species could permit the granting of an authorisation subject to the introduction of specific procedures. The status of such authorisation whilst ensuring the safety of the product would need to be reviewed annually.

Other new provisions in the amended legislation on pharmaceuticals that are intended to provide an incentive to industry to bring products for minor indications or certain minor species on the market are the prolonged data protection of 13 years for products for use in fish or honey bees or other species designated by the Commitology procedure (Article 13 of Directive 2004/28/EC), and the obligation for the EMEA to provide assistance to companies for the submission of their application for veterinary medicinal products which have limited markets or that are intended for diseases with a regional distribution (Article 79 of Regulation 726/2004).

It is therefore obvious that there is a need to define harmonised procedures to authorise products for minor uses and minor species within the provisions of the existing legislation.

2.2. Defining a major or minor species

While the legislation recognises the lack of products for minor indications or certain "rare" species no legislative definition exists in the EU for major and minor species.

– Definition for setting MRLs

For the establishment of MRLs, the following classification for food producing animals has been made by the CVMP, based on consumption figures and considering the number of these animal species in the EU[2]:

Major food-producing species for MRLs:

- Cattle (dairy and meat animals)
- Sheep (meat animals)
- Pigs
- Chickens (including laying hens)
- *Salmonidae*

As a consequence of this definition, all the other animal species by default are classed as minor when setting MRLs. Examples of minor food-producing species considered relevant for setting MRLs:

- Other ruminants, e.g. *bovidae* including *caprinae* and their milk, deer including reindeer
- Sheep (dairy)
- Other avian species and their eggs
- Other fin fish species
- Other mammalian species (e.g. horse and rabbit)
- Honey bees

– Definition for dossier requirements for marketing authorisations

In reviewing whether the approach applied for the establishment of MRLs for the division of species into major and minor categories would be also suitable for the purpose of defining the adaptation of dossier requirements for marketing authorisations (efficacy, target animal safety and environmental

[2] Statistical data used as basis for the analysis for EU prior to enlargement in May 2004

safety and quality) it was agreed that a similar approach could be to use animal population numbers as a basis for defining minor species for that purpose.

In order to examine the possibility of setting animal population thresholds and thus establish potential minor species definitions, data on animal numbers were collected from the Member States and Eurostat (Agricultural Statistical Yearbook 1999 and 2000) and an analysis of these data was carried out.

It was agreed to consider the global animal numbers across Europe instead of basing the definition of minor species on the variation of numbers within Member States. The analysis of the data and proposals for animal population thresholds (15 million animals for mammalian species with the exception of rabbits and dairy sheep, 200 million for poultry and 100,000 tons for fish species) are explained in more detail in the Annex to this document. Based on these threshold values, the following species are defined as major:

- Cattle (dairy and meat animals)
- Sheep (meat-animals)
- Pigs
- Chickens (including laying hens)
- *Salmonidae*[3]
- Dogs
- Cats

As a consequence all other animal species by default are classed as minor. With this definition of major and minor species in respect to food-producing animals the classification previously agreed in relation to the establishment of MRLs has been confirmed.

2.3. Defining a minor use in a major species

The definitions of major or minor species are not suitable for the identification of minor uses. For example a certain disease might have a very low prevalence in a major species and therefore can be considered to be a minor use in relation to the development of a specific drug for the treatment of that disease.

The CVMP has considered the possibility to establish a threshold value to define minor uses. The proposal to base the definition on the number of cases treated as in the human sector had to be dismissed because this type of epidemiological data is not reliably available in the EU. An alternative proposal to establish a threshold based on product sale values was considered. However this was not a feasible option, because of the difficulties in obtaining any useful data. The only practical approach at present seems to identify a minor use on a case-by-case basis once the company has submitted documentation to support the minor use of a product. As the starting point, the importance of the product in question to avoid animal suffering, production losses due to the non-availability of treatment, as well as estimates of future market sales should be taken into account.

In deciding of any minor uses claim also ethical considerations such as sustainable breeding may need to be considered as criterion.

No separate scientific expert body should be established for the minor use approvals, which should be considered by the CVMP with the support of an advisory group, if appropriate. Once experience had been gained criteria could be defined.

[3] It is recognised that marketing authorisations covering several salmonid species the data requirements for the second and further species would depend e.g. on the indication and the route of administration, and should be decided on a case-by-case basis

3. ACTIVITIES UNDERTAKEN BY CVMP

The CVMP has addressed the possibilities to facilitate the establishment of MRLs for minor species since several years. The status on these activities is as follows:

Major species require a full data set for the establishment of MRLs. The CVMP and its ad hoc group on availability have considered extensively the possibilities for extrapolation of MRLs from major species to other species. If the substance is used for a major species the extrapolation of the MRLs to the corresponding minor species of the same class can be made using limited data (*Note for Guidance on the Establishment of Maximum Residue Limits for Minor Animal Species* EMEA/CVMP/153a/97, *Note for guidance on the Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin* EMEA/CVMP/187/00-FINAL), or to all species providing that there are similar MRLs established for tissues for the three major species - cattle or sheep, pigs and chicken or poultry (*Note for guidance on the Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin* EMEA/CVMP/187/00-FINAL). The CVMP makes continuous efforts to find means to establish MRLs for substances which are considered essential for food-producing animals both in respect to substances for which MRLs have been set in major species but where they are lacking in minor species, and for substances for which no MRL could be set at all (see *Position Paper on Availability of Veterinary Medicines* EMEA/CVMP/151/99-FINAL, and updates (EMEA/CVMP/731/99-FINAL, EMEA/CVMP/130/00-FINAL and EMEA/CVMP/411/00-FINAL).

As a first step the CVMP had recommended in January 2002 that for 12 substances meeting the criteria of the Note for Guidance and qualifying for the extrapolation to the existing MRLs to all food producing species, such extensions without formal applications. Recognising that insufficient veterinary medicines are available for the treatment of sheep and goats, the CVMP agreed to extrapolate the existing MRLs in cattle and/or sheep to further ruminant species for certain substances identified as essential, mainly parasiticides and for which sufficient data were available justifying such extensions.

An abbreviated data set is required for setting of MRLs for minor species if no corresponding major species have been assessed for a certain substance (*Note for Guidance on the Establishment of Maximum Residue Limits for Minor Animal Species* - EMEA/CVMP/153a/97). This is being reviewed by the CVMP and its Safety Working Party as to whether the approach requires adaptation. However, the CVMP shares the opinion of most other Interested Parties that extrapolation of MRLs from major to minor species will not, on its own, help significantly to resolve the difficulties of non-availability and ensure the adequate provision of medicinal products.

The CVMP, therefore, acknowledges that similar activities have yet to be undertaken in respect to efficacy, safety or quality requirements of a marketing authorisation dossier and addresses this in its recommendation for strategic actions presented in section 4.

4. STRATEGIC ACTION PLAN

4.1. Short- or medium-term goals

4.1.1. Interpretation of existing legal provisions on specific obligations

The recent revision of the pharmaceutical legislation by Directive 2004/28/EC and Regulation 726/2004 confirm the provisions for marketing authorisations subject to the introduction of specific procedures, and provides for more details on the conditions under which such authorisations can be granted in exceptional circumstances. The CVMP and the EU Member States in accordance with legislation should facilitate these authorisations under exceptional circumstances of such medicines with possibly a limited data package (to be defined) and to be reviewed annually for a maximum number of years, to be determined. Similarly, the same approach should be adopted by Member States for applications through the mutual recognition procedure. The requirements for such authorisations which are to be granted for objective verifiable reasons needs to be further explored and the criteria for these legal provisions be clarified in the context of facilitating the provision of medicines for minor

uses and minor species. The CVMP is committed to assist the Commission and Member States in developing guidance for the implementation of these legal provisions.

4.1.2. Free scientific advice as a pilot project for 12 months

For applications for marketing authorisations and establishment of MRLs for products for minor uses or minor species for food producing animals the CVMP agreed, with the endorsement of the EMEA Management Board, to provide free scientific advice as a pilot project for a limited period. This provision came into effect on 15 May 2004 for a 12-month pilot phase as described in document EMEA/CVMP/1136/03-FINAL with limited funds of Euro 100,000 being made available from Community funds.

4.1.3. Extrapolation of MRLs to minor species

The short- or medium-term actions include the on-going efforts to establish MRLs for substances which are considered essential for food-producing animals in respect to substances for which MRLs have been set in major species but the MRLs are lacking in minor species and the recent CVMP recommendation to extrapolate MRLs for ten substances considered essential for the treatment of sheep and goats. The CVMP will continue to engage in further activities in this field for extrapolation of MRLs to other minor species or other areas where there is a lack of veterinary medicines for substances considered essential without having received applications for such extensions. However, the possibility should be excluded that a marketing authorisation dossier previously submitted for a major species might be re-opened and reassessed once extension to a minor species is being considered; such action would prove a disincentive to industry.

The impact of the review of Regulation 2377/90 and the legislation on residues control, in particular in case of a re-restructuring of the annexes to Regulation 2377/90, in the upcoming year have to be awaited.

4.1.4. Data requirements for marketing authorisations for products for minor uses and minor species

The CVMP will consider whether it would be feasible to adapt the data requirements (quality, safety and efficacy) for products for minor species. This should be considered in the context of both extensions of products from major to minor species and new product development uniquely for minor species.

The documentation requirements for applying for a minor use approval need first to be defined in order to also examine the particular risk *vs* the benefits and costs of the proposed product (see section 2.2 of this document). Through scientific advice, specific monographs that provide specific protocol assistance might be developed on a case-by-case basis.

It should be noted that when a marketing authorisation for a minor use or minor species based on an abbreviated dataset would be extended to a major use or major species, such extension application would need to be accompanied by a full dossier.

However, it has to be emphasised that existing data requirements can be reduced only to a certain extent as this might otherwise compromise confidence in the regulatory system, and such reductions need to be scientifically justified. Such recommendations may require consideration and approval by the Commission and EU Member States before becoming effective.

The provision of a clear indication from the users of veterinary medicines as to a definition of where the therapeutic gaps currently are is to be encouraged. Such definitions will facilitate the work of CVMP with the support and input of its working parties to clarify the requisite data to enable authorisation of such medicines.

Standard terminology for the SPC to indicate the type of authorisation or the lack of certain data may need to be developed.

The CVMP and its Working Parties first concentrated their work on data requirements for minor species dossiers for which veterinary medicinal products already exist for use in major species. The CVMP presented the outline for the issues for consideration in the consultation document. The outcome of the consideration by CVMP and its Working Parties having considered also the comments received during consultation will be published separately and a public consultation will take place on any draft guidelines on data requirements.

4.1.5. Harmonised approach from the National Regulatory Authorities

The majority of products intended for minor species do not have the possibility to obtain a marketing authorisation via the centralised procedure as this is restricted to certain types of medicines. However, the newly introduced provision in Article 3(2)(b) of Regulation 726/2004 allowing that the centralised procedure would be applicable if the granting of the authorisation of the veterinary medicinal product is in the interest of animal health at Community level widens the scope and may be applied also for minor uses and minor species products. Efforts will be undertaken by CVMP to liaise with Member States in order to obtain the commitment of the national agencies to accept the adapted data requirements and/or to agree on a common approach for authorisations of products for minor uses, as it is already applied in some Member States and to apply the new legal provisions described in 2.1 in a consistent manner. The outcome of any scientific advice procedure from CVMP when appropriate should be a basis for harmonised assessment in the mutual recognition procedure and defended on the basis of agreed CVMP standards by the Reference Member State.

The Veterinary Mutual Recognition Facilitation Group (VMRFG), and in future the Coordination Group can play an important role in achieving such harmonisation by publicising the procedure available already in some Member States to authorise products for minor species or minor uses and then to move to implementation of a new common approach throughout all 25 Member States.

The possibility of a fee waiver or reduction should be available for applications for marketing authorisations and scientific advice for products for minor species or minor uses, particularly for food producing animals. This has been shown to be beneficial in national procedures for minor uses.

All Member States should implement Article 4, paragraph 2 of Directive 2001/82/EC and Directive 2004/28/EC, respectively, which allows Member States to permit exemptions on their territory in respect of veterinary medicinal products intended solely for aquarium fish, cage birds, homing pigeons, terrarium animals and small rodents, and in the future under Directive 2004/28/EC also ferrets and rabbits kept exclusively as pets, on requirements for marketing authorisation.

4.1.6 EMEA assistance for minor use applications

The EMEA's assistance to companies for the submission of applications for veterinary medicinal products which have limited markets is likely to comprise procedural assistance and support to translation for the product literature. The details are yet to be defined.

4.2 Long-term goals

It is recognised that a review of the pharmaceuticals legislation has just taken place resulting in the introduction of new provisions aimed to overcome the availability problem. Their impact on availability has to be awaited with timely reflection in the long term on the need for a specific legal framework on Minor Uses and Minor Species possibly allowing for market exclusivity. The following proposals have been identified as long-term goals:

- Providing the centralised procedure for marketing authorisations for all products for minor uses or minor species in a mechanism analogous to the Human Orphan Drug Regulation. The CVMP confirms that in the long term such legislative provisions are an important way to provide for greater availability when supported by all Interested Parties.

- Exploring possibilities for setting MRLs for essential substances for which no MRL has not been set for any species (see *Position Paper on Availability of Veterinary Medicines* EMEA/CVMP/151/99-FINAL, and updates EMEA/CVMP/731/99-FINAL, EMEA/CVMP/130/00-FINAL and EMEA/CVMP/411/00-FINAL.

- As one of the main reasons for the problem of availability is a lack of research and development, the CVMP should be active in urging the Community to consider measures for funding for epidemiological studies to identify minor uses on the basis of animal welfare and general public health. If no Community funds are available, the possibility to find funds from Member States should be explored in order to carry out studies necessary to generate data needed for minor uses and minor species in the academic or research institutions. These data should then be made publicly available for the industry, which is willing to develop products for minor species or minor uses.

- Explore possibilities of addressing the problems, which arise out of costs incurred for industry in the EU legislative requirements for labelling and packaging.

References

Communication from the Commission to the Council and the European Parliament - 'Availability of veterinary medicinal products' of 05.12.2000 – COM(2000) 806 final

European Parliament resolution on the Commission communication to the Council and the European Parliament on availability of veterinary medicinal products (COM(2000) 806 – C5-0105/2001 – 2001/2054(COS))

Minor Use Minor Species Animal Health Act (MUMS), United States of America (H.R. 2079)

Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits for veterinary medicinal products in foodstuffs of animal origin (O.J. No L 224, 18.8.1990, p.1), as amended by Commission Regulation (EEC) No 762/92 (O.J. No. L 83, 28.3.1992, p.14), Council Regulation (EC) No 434/97 (O.J. No L 67, 7.3.1997, p. 1), and Council Regulation (EC) No 1308/99 (O.J. L 156, 23.6.1999, p.1)

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 (O.J. No L 311 of 28.11.2001, p.1)

Directive 2004/28/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/81/EC on the Community code relating to veterinary medicinal products (O.J. No L 136 of 30.4.2004, p. 58)

Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (O.J. No L 214 of 24.8.1993, p.1)

Regulation (EC) No 726/2004 of the European Parliament and 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 (O.J. No L 136 of 30.4.2004, p.1)

CVMP Note for Guidance on the Establishment of Maximum Residue Limits for Minor Animal Species, EMEA/CVMP/153a/97-FINAL

CVMP Note for guidance on the Risk Analysis Approach for Residues of Veterinary Medicinal Products in Food of Animal Origin, EMEA/CVMP/187/00-FINAL

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CVMP Position Paper regarding Availability of Veterinary Medicinal Products – Extrapolation of MRLs, EMEA/CVMP/457/03.

General criteria for granting free scientific advice in respect of supporting the research and development of veterinary medicinal products destined for minor use in major species and minor species, EMEA/CVMP/1136/03-FINAL

VEDDRA- List of Species and Breeds for Electronic reporting of adverse reactions in Veterinary Pharmacovigilance, EMEA/CVMP/553/03-FINAL

Annex

Animal species numbers in the EU

This paper considers the global animal numbers across Europe[4] and does not take into account the variation of numbers within Member States. For example, the number of goats exceeds 1,000,000 in each of Spain, Italy and Greee (approx. 85% of the European population). This approach takes account views of the pharmaceutical industry of the market place where companies will regard the potential market as that of Europe and will not judge it by Member State. Therefore, numerical thresholds should be set on an EU wide basis.

In order to examine the possibility of setting threshold numbers of animals and thus establish potential minor species definitions, data were collected from the Member States and Eurostat (Agricultural Statistical Yearbook 1999 and 2000). This information is summarised in Tables 1-3.

Table 1. *Number of food-producing animals in the European Union in December 1999 (millions of animals). Source: Eurostat.*

Cattle (total)	Dairy cow	Pig (total)	Fattening pig over 50 kg	Sheep	Goat	Chicken
83	21	124	47	96	12	1017

Table 2. *Estimates of numbers of some other food-producing animal species in the European Union (millions of animals).*

Dairy sheep	Rabbit	Deer/ Reindeer	Horse	Farmed fish (tons produced)	Turkey	Duck and goose
20	over 260 millions	0.5	2.6	430,000 tons*	115	75

* Besides, Norway produces more than all the EU countries together. Majority of produced fish in the EU is salmonids (estimate: at least 300,000 tons, thus other fish species become minor).

Table 3. *Estimates of numbers of some non- food-producing animal species in the European Union (millions of animals).*

Dog	Cat	Pet rabbit	Mink (breeding animals)	Fox (breeding animals)
41	39	Above 15*	4	0.5

* Rough estimate because lots of data missing from individual countries.

When examining the European population data for the species and comparing it to national data for minor species it seems to be possible to set a threshold that confirms the split between major and minor species. For mammalian species in the EU a threshold value of 15 million animals could be used and this would define the following species as major (see tables 1 - 3),

[4] Statistical data used as basis for the analysis available for EU prior to enlargement in May 2004

- Cattle (dairy and meat animals)
- Sheep (meat animals)
- Pigs
- Chickens (including laying hens)
- *Salmonidae*
- Dogs
- Cats

Only exceptions to this 15 million threshold for mammalian species would be dairy sheep and rabbits. Dairy sheep should considered as minor species due to low milk yield compared to that of dairy cows. Meat- and fur-producing rabbits, which are estimated to number >260 million for meat and fur production, are considered minor species because of low financial value of animals. Estimated numbers of pet rabbits are close to the threshold of 15 million and are therefore also classified as minor species.

Different thresholds are needed for poultry and fish because of the huge animal numbers involved. In this case the threshold number should be higher: at 200 million for poultry and at 100,000 tons fish produced annually in the EU. These thresholds would place chickens and salmonids as major species and the remainder as minor species. The use of consumption figures were also considered for other animal species than for fish but it was concluded that these data are biased due to internal trade and import of food.

Bees are considered to be a special case and should be accepted as a minor species.