The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

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AVAILABILITY OF MEDICINES

As progress continues to be made by the EMEA in finalising opinions by CVMP to establish Maximum Residue Limits for remaining old substances by the deadline of 1 January 2000, there is considerable concern throughout veterinary circles in the European Union at the loss of a number of very important medicines to the detriment of animal health and welfare. This is due to a number of reasons. In the first place, many companies did not defend certain substances contained in certain niche products that were indicated for minor uses in major species or in minor species e.g. sheep, goats, rabbits, laying hens etc. for which there was little commercial return.

In addition many applications were withdrawn by companies when they received the list of questions from CVMP after the Committee's first assessment of the application, because it was considered uneconomical to invest necessary funds to generate the requisite data for what were small volume, low sale products. The CVMP has also, regrettably, been unable to reach opinions on some substances because of the inadequacy of data provided by the applicant. Finally some substances considered unsafe to the consumer at any cost have been placed in Annex IV of Council Regulation (EEC) 2377/90.
The net result of all these developments is the loss already of some substances considered essential to the practising veterinary surgeon in the treatment of animals, or the impending loss of further medicines after the deadline for setting MRLs for old substances expires after 1 January 2000.

The problem is most acute as mentioned above for minor species. In some Member States what may be a minor species in one country may be a major species e.g. sheep in southern European countries. It is now a reality that for certain of these species there are indications for which no medicinal product is legally available leading to illegal use of other medicines with likely consequences of concern for the human consumer.

The situation in the horse is also the subject of much debate in the veterinary fraternity. The horse is classed as a food animal in the Community but many products on the market prior to the entry into force of Regulation 2377/90 containing substances not defended to establish MRLs will disappear after 1st January 2000 with, according to the Federation of Veterinarians in Europe, serious consequences for health and welfare in this species.

The CVMP in April 1998 became sufficiently concerned at the seriousness of the problem that it created an ad-hoc group under the chairmanship of Professor C. Friis, Member for Denmark, to examine ways of identifying possible solutions. One of the main problems has been to accurately identify which indications in which species will not be treatable with legally available products.

The working group in collaboration with the Veterinary Mutual Recognition Facilitation group has worked hard over the last 9 months to achieve a list of these therapeutic gaps for which substances are unlikely to be available after 1 January 2000. As part of this exercise it has also become apparent that in some minor species in certain Member States, some indications can be identified for which medicines have never been available and treatment was only possible through a loose interpretation of the cascade system provided for in Article 4.4 of Council Directive (EEC) 81/851; this cannot continue.

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The EMEA Management Board has also been made aware of the problem due in part to some intense lobbying of certain of its members by a wide range of interested parties. At its June 1998 meeting it held a brainstorming session (rapporteur Dr Kothmann – member from Germany) and called upon the CVMP to advance its efforts as quickly as possible to find ways of addressing the problem within current legislation. In addition the Commission was requested to investigate possible measures to find solutions at a political and legal level.

The Commission representative (DGIII) present at the Management Board meeting agreed to consider further measures the Commission might take and some suggestions submitted by EMEA have included the following:

- Creation of an European orphan drug fund in the veterinary sector financed by the Community budget to be administered by the EMEA to support provision of additional data to enable MRLs to be established for these products which have been or might otherwise be lost. Funds are also required to fund developments of products *de novo* for minor species since the pharmaceutical industry will never invest in these types of products. The amounts involved will have to be estimated once the extent of the problem is finalised.
- Relaxation of the cascade system under measures listed in Article 4.4 of Council Directive 81/851 (EEC) by an amendment to the Directive so that any products licensed in one Member State for any species, with an MRL established for the active ingredient in that species can be used in any other species within the same class (i.e. mammalian, piscine, avian) without an MRL being required in the new species. This could only be allowed where no other medicinal product is legally authorised and accompanied by sufficiently long statutory withdrawal periods.
- With the coordinated effort of colleagues from the EMEA, its CVMP and Commission Services (DG VI and DG III) to define means of identifying horses so that those used only in sporting and performance activities and not destined for the human food chain can be treated with products containing substances not having an MRL.
- Modification of Council Regulation (EEC) 2377/90 to grant protection to those companies which sponsored the residue evaluation of substance, and limited in time.

With this in mind the EMEA is anxious to make progress to find ways of resolving the current difficulties but recognises that results can only be achieved if efforts are jointly undertaken with Commission services. Progress is being made and further updates will be provided.