Reflection Paper on Residues in foodstuffs of animal origin

Introduction

The Federation of Veterinarians of Europe (FVE) is the umbrella body for veterinary organisations from more than 30 European countries.

FVE represents and promotes the veterinary profession in Europe.

FVE welcomes the initiative of the European Commission to produce a discussion paper presenting points to be considered and debated with a view to reconsider and modify Community legislation concerning residues of veterinary medicinal products (VMP’s).

FVE welcomes the fact that the Commission recognises that the present legislation has significantly contributed to a dramatic decrease of medicines availability in food producing animals.

FVE acknowledges that the use in food producing animals, of products that cannot be considered as safe for the consumers must be avoided. At the same time FVE is of the opinion that – in the interest of animal health and animal welfare - veterinary medicinal products for the prevention, the diagnosis and treatment of diseases must be legally available as widely as possible. This availability should not be limited by unnecessarily complicated rules and procedures or by lack of cooperation and coordination between legislative bodies and / or private parties.

Definition for Food-producing animals

In the introduction of the reflection paper on page 5 it is said: “none of the legislation mentioned above defines ‘food producing animals’.”

FVE has put this problem forward on several occasions and also already suggested a definition during the process of review of Directive 2001/82/EC.

We suggested that for the purpose of this Directive, food-producing animals would be defined as:

- Animals bred, raised, kept or slaughtered specifically for the purpose of producing food for human consumption, and
- Those animals, originally bred, raised and kept for sport, leisure or other purposes, from the moment when they become destined for human consumption.

At that time, the Commission could not accept this suggestion as it considered that such a definition did not fall within the scope of the pharmaceutical legislation.
However, considering that the absence of a clear definition of ‘food-producing animals’ has resulted in different interpretations as well as in difficulties in applying the legislation, for species such as horses, and that the veterinary pharmaceutical legislation is making reference in several places to food-producing animals, for which additional measures must be taken to protect consumers from residues of medicinal products, FVE believes that such a definition is essential.

**Impact of the application of Regulation 2377/90 on the availability of veterinary medicinal products**

It is clear that the requirement in Directive 2001/82/EC of inclusion of a pharmacologically active substance in annexes I, II or III of Regulation 2377/90 as a precondition for obtaining a marketing authorisation for VMP’s for food-producing animals did have an enormous impact on the availability of such products.

For substances to be included in one of these annexes, a pharmaceutical company has to apply for the establishment of an MRL and to produce a comprehensive dossier with data on pharmacology, toxicology, pharmacokinetics and residues. To obtain these data, the company has to invest in large and expensive studies, often without clear expectations about a return on investment. As a result of this, many pharmaceutical companies decided not to apply for the establishment of an MRL for certain substances, thus withdrawing VMP’s from the market. This is especially the case for substances used in VMP’s for minor uses and minor species (MUMS) where the market is small.

One of the suggestions the FVE would like to make is to find ways to make it more interesting for pharmaceutical companies to start these applications. For example differences in evaluation of dossiers by national authorities and requests for additional studies should be avoided.

At present, complete pharmacokinetics studies have to be performed for each substance and for each species, again. However, studies in other species and from substances with similar pharmacokinetic characteristics could be used to obtain information necessary for assessing the safety of a product.

Furthermore, in our opinion it should be possible to reduce pre authorization efficacy tests, since the efficacy could also be evaluated in the course of a step by step provisional marketing authorisation process. This would then mean that the monitoring of the efficacy and safety of the VMP’s on the market should be improved by improving pharmacovigilance measures.

**Mutual recognition**

Under EU legislation, practitioners can only use products authorised in the Member States where they work. If no product is authorised in their country, but is available in another EU country, they are not allowed to use this product on a regular basis. Exceptions are foreseen in the review of Directive 2001/82/EC in specific cases by using the “cascade”. Even though the FVE welcomes this first step, it is not seen as a practical way forward since this would always only be under exceptional circumstances.

It is difficult to understand why, when no suitable product is available in one country, a practitioner could not use a product imported from another EU Member State, where it is authorised. Consumer protection can not be an argument, in this particular case, as carcasses, eggs and milk, with their residues, can anyhow move freely within the EU single
market. Quality, efficacy or target animal safety are also poor arguments, as rules have been harmonised since 1981 and procedures are common to all countries since 1995.

In our opinion, the effectiveness of the mutual recognition system should be improved and VMP’s authorised in one Member State should easily be recognised in other Member States.

Withdrawal time and the concept of half-life

In 1999, the CVMP concluded that a withdrawal period of 6 month for substances without an MRL was largely sufficient to guarantee the protection of consumer health. In Directive 2001/82/EC a withdrawal period of 28 days for meat from poultry and mammals is set for substances included in Annex I, II or III to Regulation 2377/90 used under the Cascade. This is unless the medicinal product used indicates a withdrawal period for the species concerned.

These periods can cause practical problems for species that are produced in a short period and might not always be necessary. Especially when substances have a short half-life, it might be possible to set shorter withdrawal periods, long enough to protect consumers from harmful residues.

The question here is, whether it is possible to establish withdrawal periods for minor species if a withdrawal period for major species has been set? We could look at the experience in FARAD and the US system based on withdrawal time and the concept of half-life.