

## **PRESS RELEASE**

### **IFAH-Europe welcomes Commission's modified Veterinary Directive proposal**

**Brussels, Belgium, 28 April 2003:** IFAH-Europe broadly welcomes the European Commission's modified proposal for amendments to Directive 2001/82/EC on the community code relating to veterinary medicinal products released on 24 April 2003.

Commenting on the modified proposal Dr Delforge, IFAH-Europe Chairman, said, "We are pleased that the Commission has issued these long awaited amendments. In particular we note that the Commission has retained its original proposal for a harmonised 10-year data protection period. This supports IFAH-Europe's belief that adequate and fair data protection is essential for the industry to be able to develop new products to fill existing therapeutic gaps, for the benefit of both animal welfare and consumer safety."

#### **FURTHER INFORMATION**

IFAH-Europe acknowledges the European Commission's eagerly awaited modified proposal for amendments to Directive 2001/82/EC on the Community code relating to veterinary medicinal products ('veterinary Directive'), released on 24<sup>th</sup> April 2003. In a generally balanced approach, the Commission has accepted several important improvements to the legislative texts proposed by Parliament.

The release of the modified proposal has been pending ever since the end of Parliament's first reading in plenary session on 23<sup>rd</sup> October 2002, when it adopted a final report on the Commission proposals.

In its response to Parliament's report on the veterinary Directive, the Commission has fully accepted 16 of Parliament's proposed amendments, accepted in part or 'in principle' a further 20, and rejected 26. In addition the Commission's modified proposal contains a further 19 new amendments that were required to bring the veterinary Directive in line with amendments accepted by the Commission in the modified proposal for 'human Directive' (Directive 2001/83/EC on the Community code relating to human medicinal products).

Of particular interest are the provisions in the veterinary Directive relating to the period of validity of marketing authorisations, the 5-yearly marketing authorisation renewal process, and data protection.

Taking the first of these issues, the Commission has accepted that the proposed two-year deadline for placing a product on the market following the granting of a marketing authorisation (MA) should be extended to three years, and a clause should be introduced to allow for exceptional circumstances. IFAH-Europe believes that this clause should be deleted, or at least extended to five-years to be equivalent to the current period of MA validity.

On the second issue, the proposal from the Commission, which had the full support of industry and several regulatory authorities, was that 5-year renewals should be deleted. The response of Parliament was very mixed, resulting in a compromise amendment for a single 5-year renewal, including a reassessment of the benefit:risk ratio of the product, after which the MA would become valid indefinitely. The Commission has accepted this proposal, but has also added the requirement for a consolidated dossier, with all the variations introduced in the previous 5 years to be submitted for the renewal. It is unclear however whether this means a simple consolidated list of all the changes or if this will require a complete reformatted dossier. The latter would represent a new large bureaucratic burden to both the competent authorities and the marketing authorisation holder, without benefiting animal welfare and consumer safety.

On the third issue, the current levels of regulatory data protection are either 6 years for 7 member states or ten years for the remaining 8 member states and the centralised procedure. The Commission has proposed that this period is harmonised to 10 years. Parliament refined

this proposal by agreeing to a harmonised 10-year *market exclusivity* period, but a reduction in the actual period of regulatory *data protection* to 8 years, so that an application for a generic product could be submitted in year 8, but could not be marketed until after the 10-year period had expired. The Commission has not adopted this in its modified proposals, as it considers the balance between stimulating innovation and allowing reasonable access for generics was achieved in its original set of proposals. The research-based animal health industry supports this view, arguing that in shortening the period of regulatory data protection much-needed innovation and new product development will suffer.

The modified proposals from the Commission also raise the following additional concerns for industry:

- the Commission has rejected the Parliament amendment to article 67, concerning prescription only medicines, which aimed at preserving the existing national arrangements for the classification systems for medicinal products for food-producing species. The Parliament position had been welcomed by IFAH-Europe, as it would allow each member state to continue to take responsibility for animal welfare and food safety in their region.
- the Commission has accepted that manufacturing site inspections can be unannounced; IFAH-Europe believes that at least some prior notice would be good practice, and would replicate practices in other allied and regulated industries.
- the Commission has accepted that marketing authorisation holders should not be allowed to communicate pharmacovigilance information to the public without the consent of the competent authority. IFAH-Europe requires clarification about the audience the Commission is targeting and has concerns lest that this may prevent direct discussion with customers who contact them with a pharmacovigilance issue.
- the Commission has broadened the definition of a generic. IFAH-Europe calls for further clarification on this definition and its application.

However IFAH-Europe does welcome the rejection by the Commission of certain of Parliament's suggestions, in particular proposals -

- to ban the advertising prescription only medicines to the general public (except where these contain narcotic or psychotropic substances) and

- that veterinary medicinal products for food-producing animals should be authorised “for therapeutic purposes only”, as the definition of medicinal product is broader than just therapy (e.g. vaccines).

**--Ends--**

Notes to Editors: IFAH-Europe is the representative body of manufacturers of veterinary medicines, vaccines and other animal health products in Europe. It is a major operating division of a broader organisation – the International Federation for Animal Health, an international not for profit organisation registered under Belgian law.

For further information on IFAH and IFAH-Europe including a list of members please see <http://www.ifahsec.org/>

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