PHARMACEUTICAL COMMITTEE

AND VETERINARY PHARMACEUTICAL COMMITTEE

Information on the outcome of the 2nd special meeting on the Review 5th July 2001

OPENING

Mr Paul Weissenberg opened the meeting. He chaired the meeting on points 1.1,1.2, 1.5, 1.6 and point 2.

AGENDA

The draft agenda of the 2nd special meeting (PHARM 358) was adopted. It was agreed to discuss first the proposals to amend Regulation 2309/93 and then the changes to the two codified Directives.

1. CONTENTS OF THE REVIEW

After a brief introduction by the Commission representative, the Member States presented general remarks on the proposed amendments and identified several key-issues to be addressed during the meeting. It was agreed to focus the discussion on the following issues:

1.1 Centralised procedure: scope and EMEA Management Board

The proposal to make the centralised procedure obligatory for all new active substances was criticised by a number of Member States. They claimed that the centralised procedure should be obligatory only for highly innovative products and that for other products there should be flexibility between the centralised and the decentralised procedure. During the discussion it was pointed out that the term "new active substance" was open to interpretation. It should be better defined so that it is limited to "really" innovative substances. The difficulties of applying such a solution in the veterinary sector were also emphasised.

Concerning the proposed composition of the Management Board of the EMEA, a majority of Member States disagreed with the proposal and were in favour of at least one representative per Member State.

The Commission representative clarified that a "new active substance" would relate to such active substance not yet contained in a medicinal product authorised in any Member State. The proposal would aim at better achieving public health, in particular with regard to the forthcoming enlargement of the Union. The Commission representative also explained that the reason for the envisaged structure of the EMEA Management Board would be to have analogous administrative provisions for all the Community Agencies, in particular taking into consideration the last three Agencies, currently discussed in the European Parliament and the Council. However, in case of modifications in these other sectors, the proposed structure may be altered again.

1.2 Mutual recognition procedure

There was general support for the modifications introduced. In particular, the Member States were in favour to differentiate the situations where a marketing authorisation already exists from those where this is not the case. The idea of forced arbitration was also welcomed, as was the explicit legal basis for a group dealing with the mutual recognition and decentralised procedures. However, there was general concern about the proposed timeframes and time reductions.

The Commission representative explained that the envisaged reductions of time limits only affect the evaluation phase, but not the mutual recognition phase, and that the proposals only return to the original time limits in force until 1995.

1.3 Harmonisation of legal status

The discussion showed general concern on the part of the Member States. The classification of a medicinal product would largely fall into the competencies of the Member States. Together with the different national policies, this would render a harmonisation in this area very difficult.

1.4 Renewals

The Commission representative explained that the proposed indefinite validity of Community and national marketing authorisations would be motivated by the fact that the renewal very often would be a mere administrative act without proper re-evaluation of the dossier. To ensure full post-authorisation control, a number of related provisions would be introduced or amended, including the lapse of the authorisation in case of non-marketing of the product, the frequency of the periodic safety update reports and measures connected with safety restrictions.

The Member States were divided on these proposals. Some fully agreed with the Commission's assessment and the proposed amendments. Others maintained that the renewal procedures would be appropriate and even necessary to maintain full post-marketing control.

1.5 Generics: data protection and "Bolar"

The Commission representative outlined the main modifications with regard to generic medicinal products. The concept of "generic medicinal product" would be introduced and defined explicitly. The data protection period would be harmonised on the level of 10 years for all products. An additional year of protection could be obtained where certain new indications are authorised. As trade-off, a so-called "Bolar" provision would be introduced, allowing the preparation of generic applications while the reference medicinal product is still protected by patents or supplementary protection certificates.

Most Member States sustained the proposals. However, some disagreed with the additional year of data protection. Doubts were also expressed how the new indications justifying additional protection could be defined.

1.6 Advertising/information

In introducing this subject, the Commission representative pointed out that despite the existing ban of advertising for prescription-only medicines in Europe, an increasing amount of information is available on these products, in particular via internet. It would be proposed to prudently lift this ban so as to make available on the demand of patient groups certain information under strict conditions and control. During a test case of 5 years, information would be allowed for medicinal products for three types of diseases, where it respects principles to be laid down. The effects would need in-depth analysis after 5 years.

In general there was agreement amongst the Member States that the current total ban cannot be maintained, but that a complete freedom of DTC advertising for prescription-only medicines would neither be acceptable. The further assessment by the Member States was diverging. While some felt that no test case should be allowed, others agreed with the proposals and even asked for an extension to orphan medicinal products.

1.7 Compassionate use

The Commission representative explained that the proposals aim at a more formalised and harmonised approach to the availability of medicinal products on a compassionate use basis.

Some Member States point out that neither the compassionate use nor other kind of conditional marketing authorisations must lead to a situation where unsafe products arrive on the market.

1.8 Specific changes relating to veterinary medicinal products

The comments from Member States on the major specific proposals regarding veterinary medicinal products mainly focused on the planned obligation for prescription of veterinary medicinal products for food producing animals. The majority of the Member States agreed with the Commission proposal. Only some representatives argued that this could lead to potential difficulties in their countries. The Commission representative explained that this provision was in line with the overall objective of the pharmaceutical legislation to protect public health. Furthermore, surveillance and monitoring of the use of veterinary medicinal products would be facilitated by this measure.

There were also some minor comments on the cascade, time limits for keeping documentation and the proposed lapse of a marketing authorisation where it is not followed by an effective marketing of the product within two years.

The discussion also concerned the special data protection granted to medicinal products for fish and bees and the possibility of having it extended to other minor species. The Commission representative explained the different modalities for data protection provided for in the proposals and confirmed that veterinary medicinal products aimed at other minor species could also benefit from the proposed changes.

1.9 AOB

The proposal to allow therapeutic indications for registered homeopathic medicinal products was criticised by one Member State.

The Council of Europe representative raised some specific issues concerning the European Pharmacopoeia.

2. PROCEDURE

The Commission representative informed that the codified Directives would probably be approved by the Council during the month of July. The legislative proposals for amending Regulation 2309/93 and the two codified Directives are scheduled for approval by the Commission on the 18th July.