JOINT HUMAN AND VETERINARY PHARMACEUTICAL COMMITTEES

Information on the outcome of the Special Meeting on the "Review"

27th November 2000

The summary record follows the structure of the two documents PHARM 331 and VETPHARM 199, which the Commission services had prepared as a first basis for reflection and discussion.

A. ISSUES RELATING TO HUMAN AND VETERINARY MEDICINAL PRODUCTS

I. Objectives of the review

In general, the five main goals of amending the pharmaceutical legislation, as indicated in the discussion paper, were supported. It was agreed that further aspects should be mentioned within the five general objectives and that further objectives will be added, e.g. animal welfare, availability of veterinary medicinal products and reinforcement of the pharmacovigilance system.

II. Centralised procedure

The assessment, based on the report by Cameron McKenna/Andersen, that the centralised procedure has fulfilled its role with notable success, was widely shared. The discussion focussed on the following points:

1. **Field of application** of the centralised procedure:

With regard to the authorisation of **new medicinal products**, some Member States supported the suggestion of the reflection document, to maintain list A but to remove list B, by giving full optionality to products not covered by list A. This compromise would allow the reinforcement of the idea of flexibility, competition and incentives while guaranteeing an appropriate scientific assessment. Stressing the element of flexibility and competition, other Member States proposed to delete both lists A and B so that the firms could opt either for the central or for the mutual recognition procedure for all medicinal products. Other Member States pointed to the necessity of adequate scientific assessment and were strictly opposed to free choice in this area. Instead, they opted for the retention of both lists in principle as they stand at the moment, apart from minor changes.

With regard to the authorisation of **generic medicinal products**, some Member States agreed with the proposal contained in the reflection document to authorise generics according to the same procedure as the original product. Where the "reference product" had been authorised centrally, the producer of the generic medicinal product should at least be given an option to use either the centralised or the decentralised procedure. Other Member States would prefer to authorise generic medicinal products exclusively on the

national level, so as to reserve the centralised procedure to new and specifically sensitive products. No clear conclusion was reached on this point. The Commission representative insisted on the need to find a compromise, which would keep the same level of protection of public health while ensuring certain flexibility to the system.

2. The idea of providing **increased scientific advice** to pharmaceutical companies was largely supported. A number of Member States pointed to the need to ensure sufficient capacity for scientific assessment and advice at national level. Only by establishing close "networks" of information and scientific exchange between the agencies on national and Community level could the same high level of protection within both procedures be guaranteed.

3. Concerning the **fast track procedure**, some Member States showed reluctance to set up accelerated authorisations. They insisted on the importance of increasing advice to the firms at an early stage of the procedures and of reducing the time limits. As an alternative to a fast track procedure, an authorisation could be granted for a limited time. With regard to a system of **compassionate use**, while acknowledging certain Community competences in principle, a number of Member States claimed that this question should fall into the national competences. It was also proposed that a continued use of medicinal products for individual patients be allowed, where the product has completed clinical trials.

III. Mutual recognition procedure

The view was commonly expressed that the mutual recognition procedure also worked satisfactorily, while recognising the need to keep the two systems of centralised and decentralised authorisations in place. The need for improvement and confidence building was highlighted. The discussion focussed on the following specific points:

1. Member States strongly opposed the idea of **shortening the time limit** of 90 days as laid down in Article 9(4) of Directive 75/319/EEC. They consider this time period indispensable to enable proper dossier analysis in line with their public health responsibilities. If it were cut down, many would feel compelled to refuse mutual recognition. However, some Member States pointed towards a possible compromise in that they could accept a reduction of the period of 55 days for raising objections to 45 days, leaving a further 45 days for a solution.

2. The suggestion to **improve co-operation and information** between Member States and their experts was welcomed. As mentioned in the context of the centralised procedure, the Member States attach great importance to an improved "network" of national agencies and experts in both procedures.

3. Similarly, the Member States were in favour of the suggestion to **clarify the public health requirements** justifying a refusal of the mutual recognition. However, some

Member States expressed doubts whether it will be possible to find sufficiently clear criteria, acceptable to all Member States.

4. The Commission services' suggestion, to grant a Community authorisation where the mutual recognition of an original medicinal product is refused, while maintaining the existing arbitration for generic medicinal products (possibly a "selective arbitration"), was supported by some Member States. Others rather would restrict the **arbitration procedure** to those Member States, which have raised objections, while granting an authorisation in the other countries. Another proposal was to split the procedure with the result that only the contentious part enters the arbitration procedure. Some Member States finally would like to deprive the firms of the right to withdraw the application and replace it by an obligatory arbitration.

5. The intention to progressively **harmonise generic medicinal products** by agreeing upon "core SPCs" was in general supported by the Member States.

IV. EMEA

The Commission services presented the new proposal for setting up a European Food Authority, as far as the institutional structure is concerned. It could have some consequences on the future proposal concerning EMEA administrative structures. The idea to decrease the number of members of the scientific committees and of the management board to one per Member State was criticised because this would prevent a sufficient representation of the various scientific disciplines. Others supported the proposal, arguing that it would not be necessary for each discipline to be represented by each Member State. The suggestion to set up scientific panels was generally supported. Some Member States expressed the view that the members of these panels should fulfil a double role at Community and national level and that attention should be paid more to the expertise membership than to the representativity.

V. Decision making process

The Member States' opinions on whether or not to replace the current decision making procedure were divided. The procedure will in any event need to be in line with the new EC decision on comitology procedures.

B. SPECIFIC ISSUES WITH REGARD TO VETERINARY MEDICINAL PRODUCTS

The intention to improve the availability of veterinary medicinal products was generally supported. Especially the extension of the field of application of the so-called cascade in the sense of Article 4 (4) of Directive 81/851/EEC and the Regulation 2377/70 on MRLs were discussed, though without mentioning concrete proposals. Some Member States expressed the view that the decision process might be improved, if the MRL were considered as early as possible in the authorisation procedure.

C. ANY OTHER BUSSINESS

Further suggestions of the Member States were: to modify the existing definitions, to transfer parts of the Notice to Applicants with legislative character in proper legislative acts, to stipulate parallel imports, to clarify the provisions of Articles 11 and 12 of Directive 75/319/EEC and to enhance the protection of improvements to existing products. It was also demanded that data protection provisions between the centralised and the decentralised procedure be harmonised.

On the draft directive on herbal medicinal products, the Commission will seek the scientific advice of the EMEA and will at a later stage present the draft in the Pharmaceutical Committee for discussion.

The future participation of candidate countries at meetings of the Committees on the review was discussed.

D. FURTHER STEPS OF THE REVIEW

On the basis of the documents PHARM 331 and VETPHARM 199 and the discussion in the joint meeting, the Commission services will prepare a modified "reflection paper". It was indicated that there might be a public hearing with interested parties on the subject.[1] The Commission services announced the intention to present a first draft of the legislative acts to be reviewed during the first half of 2001.

[1] It has been decided that the public hearing will take place on the 26th January 2001.