PHARMACEUTICAL COMMITTEE
Information on the outcome of the 51st meeting
5th April 2001

OPENING

Mr Paul Weissenberg, Director of Directorate F of DG Enterprise, opened the meeting. He especially welcomed the representatives of the candidate countries, which had been invited to participate as observers for the first time. Eight candidate countries had accepted the invitation and were represented during the meeting.

Mr Weissenberg chaired the discussions on points 2.3, 2.6, 2.7, 2.8, 6, 8.1, 8.2 and parts of point 9.

AGENDA

The draft agenda of the 51st meeting (PHARM 333) was adopted. Following requests from members of the Committee, a new item relating to the case C-454/00 concerning the interpretation of Regulation No. 1768/92 on supplementary protection certificates was added under point 1.1. Furthermore, two new items relating to the High Level Group on Innovation and the Provision of Medicines "G10" as well as on the working group on electronic commerce were added under point 9.

SUMMARY RECORD

The summary record of the 50th meeting on 21-22 September 2000 (PHARM 334) was adopted without amendment.

The summary record of the joint Human and Veterinary Pharmaceutical Committees on 27th November 2000 (PHARM 332) was adopted with the following amendment: In the first sentence of the introduction to point III (Mutual recognition procedure), the words "does not work satisfactorily" are replaced by "also worked satisfactorily".

On request of the Dutch representative it was agreed that the draft summary records would be sent to the Member States for remarks before publication on the Commission's website.

1. INTERPRETATION/IMPLEMENTATION OF LEGISLATION

1.1 Information on pending cases

The Commission representatives updated the Committee on progress in the following procedures:

In case C-424/99 concerning an action brought by the Commission against Austria for incorrect implementation of the "Transparency" Directive 89/105/EEC the hearing before the Court took place on 28th March 2001. The decision is to be expected soon.

In case C-229/00 the Commission alleges that the Finish legislation and administrative practice is not in line with Directive 89/105/EEC. The written procedure is closed. The Court has to decide whether there will be an oral hearing.

In case C-321/00 where Germany has filed an action for annulment of Commission Directive 2000/38/EC on pharmacovigilance, the Commission is currently preparing the rejoinder.

In case C-433/00, a German court has asked for a preliminary ruling by the Court on the questions of rebundling and repackaging of centrally authorised medicinal products. The Commission sent its observations on 12th March 2001.

In cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T-137/00, T-141/00, T-147/00 concerning Commission decisions on withdrawing marketing authorisations for medicinal products containing anorectic substances, the Court of First Instance has issued a preliminary suspension of the Commission decisions. With the exception of T-74/00 (Artegodan), the Commission appealed against these orders of the Court of Justice.*

The French representative asked the Commission about its opinion in the case C-454/00. The Commission services agreed to reply either in written or orally during the next Pharmaceutical Committee.

1.2 Orphan medicinal products

The Commission representative informed the Committee that the first detailed inventory of incentives for orphan medicinal products, put in place by the Member States and the Community, had been published. Finland and the EMEA provided information on further incentive measures. The Commission representative declared the intention to elaborate an interpretative communication on Regulation No. 141/2000 before end of 2001.

2. LEGISLATIVE ISSUES

2.1 Directive on Clinical Trials

The new Directive on Clinical Trials was finally adopted by the Council and the European Parliament on the 4th April 2001 and will be published soon, as the Commission representative explained. It will have to be implemented by the Member States within 36 months. The EMEA has started to analyse the practical consequences, especially the need for a new database for clinical trials.

2.2 Directive on Food Supplements

The Commission representative briefly introduced the subject by explaining the last amendments adopted by the Commission following the European Parliament's first reading. Member States expressed the concern that on the basis of the current wording of the Directive ("physiological") it will be difficult to decide whether a product has to be

* In the cases T-76/00R (Bruno Farmaceutici), T-83/00 R I (Hänseler), T-83/00 R II (Schuck), T-84/00 (Roussel Diamant), T-85/00 R (Roussel Iberica), T-137/00 R (Cambridge) and T-141/00 R (Trenker), the Court of Justice has repealed the orders of the Court of First Instance by orders of 11 April 2001.

considered as a food supplement or as a medicinal product. It would be possible that the same product be classified differently in the Member States. Nonetheless, some Member States explicitly welcomed the new Directive.

2.3 Draft Directive on Traditional Medicinal Products

The Commission representative introduced the subject by describing briefly the main amendments to the revised draft Directive on Traditional Medicinal Products. The Member States largely appreciated the amended version. The underlying ideas as well as the structure and contents of the provisions were generally supported. A number of interpretative questions were asked and some proposals to amend the text were made. Some Member States still wanted to reflect on the revised draft so that all members of the Committee were granted the possibility to present written observations until end of April. On the basis of the discussion and the written remarks, the Commission services will consider to issuing an amended draft and starting inter-service consultations in May.

2.4 Master file concept

The subject of a possible vaccine antigen master file was introduced by presentations by France on the general principles and Belgium on some concrete examples. The underlying idea of evaluating a vaccine antigen independently to an actual application for a European or national marketing authorisation was generally supported. Spain however declared that they would need to discuss internally before an official opinion could be delivered. The Commission representative indicated that a number of legal texts would have to be changed on the European as well as on the national level. The NTA group will further analyse the feasibility of the concept. A more concrete text shall be elaborated. It will be presented to the next Pharmaceutical Committee for further discussion.

The Commission representative then introduced the plasma master file concept, which had been discussed at a previous meeting. It was explained that the fundamental idea of a single and independent evaluation on the Community level would be very similar to that in the vaccine antigen master file. The Member States generally supported the concept.

The Biotech WP of the EMEA will re-examine the plasma master file concept and deliver an opinion in May 2001. Afterwards the NTA group will investigate the two concepts in detail. The Member States agreed with this approach and the underlying concepts.

2.5 Variations regulations

The Commission representative updated the Committee on this subject and indicated that a modification of the regulations on variations and most particularly the concept of a variation “type 0”/”tell and do” is under re-consideration at the moment. The amendments to the existing legislation shall be concluded by end of 2001.

2.6 TSE

The Commission representative introduced the subject. In the following discussion, some Member States explained the status of updating the information of the medicinal products on their national markets. The principles as set out by the Community were explicitly supported. The EDQM and the Member States agreed that the EDQM has to focus on priority areas to issue the most relevant certificates as soon as possible. The EDQM explained that the certificates are prepared at the moment, but that better communication with the Member States including more information from them would be needed. The Commission representative reminded the Member States to answer the letter sent to them recently (PHARM 356c). The Member States agreed to present the information on the current status of practical implementation of the TSE provisions.

2.7 Starting materials

The Commission representative explained that starting materials would be dealt with in the review. The general contents of the envisaged provisions were outlined. Some Member States would have preferred a separate legal act on this subject and indicated their wish to extend the new regime on starting materials to other starting materials in addition to active pharmaceutical ingredients. The Commission representative clarified that it was expected that the envisaged provisions would be extended, if necessary, to other substances later.

2.8 Codification

Introducing this subject, the Commission representative explained the state of play of the legislative procedures of the human and the veterinary codification. If there were no unexpected objections by the Member States, the two texts could be technically ready by end of May 2001. The Member States declared not to have major problems with the two drafts as modified following various negotiations. The Commission services were called upon to keep the Member States informed of progress on the codification.

2.9 Review

The Commission representative indicated that the review of the pharmaceutical legislation would be dealt with in detail in a further special joint meeting of the two pharmaceutical committees on the 31st May 2001. Depending on the progress with the two codified texts, this meeting will be based either on a concrete proposal for amending the existing legislation that might not be approved by the Commission by that time or on a modified reflection paper. Some Member States asked the Commission for more information on progress on the review.

3. MARKETING AUTHORISATION PROCEDURES

3.1 Mutual recognition procedure

The Swedish representative updated the Committee on the state of play of the mutual recognition procedure and pointed especially to the gradually increasing number of

products using this procedure. The UK representative congratulated the MRFG for the enormous work accomplished.

3.2 Centralised procedure

The EMEA representative introduced a report on the situation of the centralised procedure and its operation by the EMEA. He expressed the EMEA's intention to further improve transparency in the post-authorisation phase. The work-programme 2001/2002 has been adopted. The EMEA expects an important increase of workload, inter alia in the sector of orphan medicinal products. This would mean an increased workload for the national experts of the Member States too.

The Commission representative invited the candidate countries to present some data on the functioning of granting national marketing authorisations in the candidate countries following marketing authorisations granted by the Commission. The Czech representative declared on behalf of the CADREAC countries that they would try to supply this information soon.

With regard to the parallel distribution of centrally authorised products, the Commission representative explained that this subject would be dealt with in the review. It is envisaged to enact specific provisions on an obligatory control of such parallel distribution by the EMEA.

3.3 Notice to Applicants (NTA)

The Commission representative updated the Committee on developments in the NTA. The revised chapter 4 on the centralised procedure of volume 2A of the NTA will be published on the website (http://pharmacos.eudra.org/) soon. Volume 2B on the presentation and content of the dossier has been completely revised to take the CTD into account. A scheme indicating the differences between the old and the new presentations will be published soon.

The Commission representative announced that the Pharmaceuticals Unit would publish the documents contained in the volumes of EudraLex as CD-ROM in the future.

4. GOOD MANUFACTURING PRACTICE

The Commission representative briefly introduced the two new annexes to the EU Guide on GMP, namely annex 15 on principles of qualification and validation applicable to manufacturers of medicinal products and annex 16 on certification by a qualified person and batch release. The two annexes were adopted unanimously.

The Commission representative then outlined a joint audit programme for evaluating national inspection systems which had prepared within the framework of the Heads of Agencies. It was explained that the objective of this programme was not to verify the correct legal implementation of the relevant EU legislation, but implementation in practice.

5. EXPORT CERTIFICATES

In the introduction of this subject, the Commission representative pointed to important divergences existing between the practice in the various Member States and asked the Member States to assess the feasibility of further analysing this issue. It was explained that reference to the WHO certificates would not be helpful, since problems with them in the past lead to the reflection on whether separate export certificates within the Community should be developed. On the request of the Member States, the Commission services agreed to analyse the differences in the Member States' practice and to evaluate the need for a possible degree of harmonisation.

6. TELEMATICS

The Commission representative introduced this subject briefly. On request of the Member States, the Commission services handed out copies of the preliminary draft of the implementation plan. The Committee welcomed the principles and structure as set out in the strategy paper (PHARM 352a). The EMEA representative made clear that a greater involvement of the EMEA in developing telematics would be possible in principle. However, on a short-term basis, the EMEA did not have sufficient resources to take over enlarged responsibilities. As from 2003 on, the role of the EMEA could be broadened if the budget were adapted. The Commission representative underlined that for the time between 2001 and 2003 a realistic and modest approach would have to be followed. On the 20th April, the Swedish Presidency and the EMEA will hold a workshop on telematics in pharmaceuticals to which the EMEA representative invited the participants of the Committee.

7. MEDDRA

The Commission representative briefly updated the Committee on the progress in this sector. Following a successful training session in March, a further training session later in the year was envisaged. A number of details relating to this additional training session still need to be clarified.

8. INTERNATIONAL ASPECTS AND ENLARGEMENT

8.1 ICH

The Commission representative explained that the major progress at ICH 5 had been agreement on CTD, and that the current challenge was its consistent implementation. The next ICH Meeting will take place in Tokyo and will be preceded by a meeting on biotech and Gene therapy. The US FDA had confirmed that they were now ready to discuss gene therapy further in an active manner. Future priority areas for the ICH would include the implementation of the CTD, and discussions on new technologies such as gene therapy.

8.2 Mutual Recognition Agreements

The Commission representative provided an update of the various MRAs in progress. She informed the Committee that the Council had signed the MRA with Japan on the 4th

April. The MRA with Switzerland still has to be ratified by some Member States. With regard to the MRA with the US, there is some delay in completing the transitional period. On the basis of the MRA with Canada, it was hoped that some operational work would start soon. Following a question raised by one Member State, the Commission representative agreed that the resource input to legal instruments such as MRAs had to be carefully considered and that an evaluation was underway within the Commission which would be particularly important before considering any new MRAs.

8.3 Enlargement

With regard to the PECA agreements, the Commission representative informed the Committee that such agreements have been signed with Hungary and the Czech Republic and will enter into force this year. A further agreement is under negotiation at the moment with Latvia.

The EMEA representative briefly updated on progress on PERF II. The priority action areas have been identified and the Member States were addressed to mobilise necessary resources. DG Enterprise will contact DG Enlargement to speed up the signing of the basic contract.

9. A.O.B.

High Level Group on Innovation and the Provision of Medicines – "G10"

After distribution of the press release of 26th March 2001 and the "Terms of Reference", the Commission representative explained the recent process of "G10". Two commissioners and 11 persons representing stakeholders in the pharmaceutical sector are expected to meet three times until April 2002; the first meeting took place in March 2001. The underlying idea is to report to the Commission President about how to improve the availability of medicines, to complete the Single Market in pharmaceuticals and to support innovation of European pharmaceutical industry. The group has nominated a rapporteur and a co-rapporteur for each topic. First ideas are to be expected by summer of 2001.

Electronic commerce

Regarding the issue of electronic commerce, the Swedish representative informed the meeting that there has been a common meeting with the Belgian authorities, who have elaborated a draft on this subject. The Belgian representative further explained that the industry has proposed the organisation of a workshop in the second half of this year. On the basis of these reflections, the principles on e-commerce would have to be fixed in writing and then be presented to the Heads of Agencies at the end of 2001.

Date of next meeting

A further exceptional joint meeting of the two pharmaceutical committees on the review will be held on the 31st May. The next regular meeting of the Pharmaceutical Committee will take place in October 2001; the precise date will be confirmed in due course.