PHARMACEUTICAL COMMITTEE
DRAFT SUMMARY RECORD OF THE 52nd MEETING
16th November 2001

OPENING

Mr Paul Weissenberg, Director of Directorate F of DG Enterprise, opened the meeting and chaired the discussions on points 5, 7, 8, 9 and 10.2.

AGENDA

The draft agenda of the 52nd meeting (PHARM 365) was adopted. Following requests by one representative, two new items were added under point 10 (A.O.B.) relating to the proposal for a Regulation concerning sales promotion in the Internal Market and to the draft Directive on human tissues and cells.

SUMMARY RECORD

The summary record of the 51st meeting on 5th April 2001 (PHARM 366) was adopted without amendment.

The summary record of the joint meeting of the Pharmaceutical Committee and the Veterinary Pharmaceutical Committee on 5th July 2001 (PHARM 367) was adopted without amendment.

1. INTERPRETATION/IMPLEMENTATION OF LEGISLATION

1.1 Information on pending cases

The Commission representatives updated the Committee on the Cases T-74/00R (Artegodan) and C-454/00 (Duphar). In Case T-74/00R, the Commission decision of 9 March 2000 is still suspended by order of the Court of First Instance of 28 June 2000. An application by the Commission to vary this order has been rejected by the Court of First Instance. The Commission has appealed against this decision to the ECJ.

Case C-454/00 concerns interpretation of Regulation 1768/92 on supplementary protection certifications. The question referred to the ECJ is whether the certificate covers only the authorised medicinal product as such or also the manufacture of the active substance contained in this product. The ECJ has not decided yet.

1.2 Implementation of Directive 1999/82/EC on TSE

The Committee was informed about the state of play of the implementation and the fact that translations of the relevant guidelines in all official languages have been published on the web site of DG Enterprise and will be published in the OJ of the EC. The Commission representative called upon the Member States to submit the information on the implementation, if not already done. She explained that regarding lactose, the Biotech

Working Group would re-analyse its explanatory note. According to the EMEA representative, for 75 of 85 centrally authorised products all necessary steps have been concluded.

2. LEGISLATIVE ISSUES

2.1 Review 2001

The Commission representative informed the Committee that the report foreseen in Article 71 of Regulation 2309/93 has been adopted and sent to the Council and European Parliament and is available on the web site of DG Enterprise. The two codifying Directives (Directive 2001/82/EC on veterinary medicinal products and Directive 2001/83/EC on human medicinal products) have been signed by the European Parliament and the Council on 6 November 2001 and would be published soon. The official proposals to amend the pharmaceutical legislation would be transmitted to the Parliament and the Council in the next days. The review of Annex I to Directive 2001/83/EC could be done by comitology and therefore does not form part of the general "Review 2001". At present, the necessary amendments to the Annex are being analysed internally within the Commission services.

2.2 Draft Directive on Traditional Herbal Medicinal Products

The Commission representative informed the Committee about the preparations done. After the adoption of the Code on human medicinal products (Directive 2001/83/EC), it appeared necessary to redraft the proposal which now takes the form of an amendment to Directive 2001/83/EC. The written procedure for adoption of the proposal by the Commission would be launched soon. Transmission to the European Parliament and the Council would be expected for end of December 2001 or beginning of January 2002.

2.3 Variations regulations

The Commission representative updated the Committee on the two proposals to amend the variation regulations. A new annex including variations for which only a notification procedure will be necessary ("tell and do") has been prepared based on a draft proposed by the Netherlands. All these documents will be discussed during the next Notice to Applicants Working Party meeting in December.

2.4 Paediatric medicines

The Commission representative updated the Committee on a first brainstorming meeting that had been held on 15 November 2001 with the participation of seven Member States, research based industry and paediatricians. There was consensus that there is a need for new medicines as well as for developing the existing ones. A consultation document will be drafted and shall be made available to the general public for a three months consultation. The legislative proposal should be ready by mid 2002.

2.5 Clinical trials Directive

The Commission representative informed the Committee that five of the ten foreseen documents (detailed guidance/guidelines) foreseen in Directive 2001/20/EC should be released for consultation soon. For the remaining documents first drafts have been prepared. The adoption procedure for these texts will depend on the individual provision of the Directive.

3. MARKETING AUTHORISATION PROCEDURES

3.1 Mutual recognition procedure

The Belgian representative updated the Committee on the mutual recognition procedure. A new version of the Heads of Agencies web site has been launched; the documents thereof have been updated. Liechtenstein has been granted the status of observer to the MRFG. With regard to the harmonisation of SmPCs, a joint CPMP/MRFG working group has been set up. Regarding the forthcoming discussions on the Review 2001, an alternative proposal for the mutual recognition procedure and the decentralised procedure is being prepared at present on the basis of the comments received by the Member States.

The figures on the mutual recognition procedure indicate that the number of procedures with only one Concerned Member State is increasing (now 27 %), whereas the number with fourteen Concerned Member States is decreasing. About 55 % of the procedures concern generic medicinal products. However, the procedures with just one Concerned Member State are very often followed by further mutual recognition procedures.

3.2 Centralised procedure

The EMEA representative updated on the state of play of the centralised procedure. He indicated that the applications for designation as orphan medicinal product are increasingly being approved. He also pointed out that the CPMP relies to an increasing extent on ad hoc expert groups. With regard to the organisation structure, one of the EMEA's priorities would be to strengthen pharmacovigilance.

3.3 Notice to Applicants

The Commission representative informed the Committee that all chapters have been updated. The chapter regarding the Commission's decision procedure still needs to be modified. The agenda for the next meeting in December includes particularly the variations legislation, the Common Technical Document (CTD) and the Marketing Authorisation Application Form.

4. GOOD MANUFACTURING PRACTICE

The Commission representative updated the Committee on new annexes and the Joint Audit Programme. Annex 13 lays down the same standards for centrally and for nationally authorised medicinal products. It has been revised in order to implement the "Detailed Guidelines" for the manufacture and the labelling of investigational medicinal

products as provided for in Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trails on medicinal products for human use. The document only takes up specific cases brought up by the inspectors. In order to avoid any misunderstanding, the wording will be clarified. The Committee was informed that minor changes to Annex 1 and Annex 7 were expected to be released for consultation soon.

5. TELEMATICS

5.1 EudraTrack

The Belgian Presidency informed about the discussions on the future of EudraTrack during the recent Telematic Steering Committee meeting in Uppsala. From 2005, once the review proposals will entry into force, the system can be run by the EMEA. For the interim period, the system needs to be maintained by a different operator. Several applications have been received.

The Commission representative explained that a template document could be drafted and presented for adoption by the Heads of Agencies. On the basis of this document, the applications would be assessed before a decision can be taken under the Spanish Presidency. The Spanish representative welcomed this idea.

5.2 EudraVigilance

The EMEA representative introduced the subject. He informed that the basic version of the EudraVigilance system would be in place on 3 December 2001 and that the Member States have been provided with the necessary software. He invited the Member States to respond to the questionnaire sent out by the EMEA on individual safety reports.

Some Member States indicated that they would be interested to apply the new system also on the national level. The Commission representative explained that such a national use would be possible on the basis of licenses to be granted by the European Commission, which would retain the property for the system.

5.3 EudraNet

The Commission representative informed the Committee that the problems, which had occurred within the EudraNet, are solved on a temporary basis. A long-term solution is being prepared at present, but requires further discussions.

6. MEDDRA

The Commission representative described the status of implementation in a number of Member States and invited those Member States, which have not already done so to inform the Commission about their projected timetables for implementing MedDRA.

7. INTERNATIONAL ASPECTS AND ENLARGEMENT

7.1 ICH

The Commission representative reported that due to the events of 11 September 2001, the Steering Committee meeting has been postponed to February 2002. She further informed the Committee on a recent Steering Committee videoconference, which had focussed on the implementation of the CTD. A first application based on the CTD format has been received. The working group on e-submission is expected to present a progress document before the end of the year. The next meeting will take place in Brussels in February 2002 and the autumn meeting of the ICH will include a workshop on gene therapy.

7.2 Mutual Recognition Agreements

The Commission representative briefly updated the Committee on the MRAs with the USA, Canada and Japan. With regard to the transitional phase in the MRA with the USA, she explained that the Commission had proposed a 2 years extension, but that negotiations with the US were ongoing.

She pointed in particular to problems for the MRA with Canada, provoked by the situation in one Member State. An investigation in that Member State by inspectors from other Member States is foreseen. An action plan has been set up but its implementation is taking longer than expected. Further time and monitoring is needed to solve the outstanding problems. The European Commission has therefore proposed a further 12 months extension of the transition period for the MRA.

7.3 Enlargement

The Commission representative briefly updated on the various PECAs and in particular the problems that have occurred to conclude the pre-operational phase activities within the designated time. It was highlighted that the PECAs can achieve their objectives of facilitating the accession to the European Union only if they enter into force well in advance of the day of accession. Therefore all efforts should be made to start with the operational phase as soon as possible. Committee representatives were invited to nominate experts to assist with the evaluation activities for Hungary.

8. AVAILABILITY OF MEDICINAL PRODUCTS IN THE CONTEXT OF BIOLOGICAL THREATS

The Commission representative explained that the objective of the questionnaires circulated to the Member States would be to make an inventory of available medicinal products and to prepare the decision on which actions need to be taken. Those Member States that had not answered yet were invited to do so soon.

In the following discussion, the Member States informed about the stockpiling exercises going on and possible measures already taken or under consideration. It was discussed in particular in how far off label use could be relied upon. In at least one Member State, a guideline is already in preparation. The Commission representatives informed that such a guideline could also be drafted on a European level and that also the provision on “named

patient" should be considered in this context. For old vaccines, companies might ask for a scientific assessment. For a long-term response, the mechanisms of Regulation 141/2000 on orphan medicinal products as well as financial subventions might be used to improve the availability of necessary medicines.

9. RELATIVE EFFECTIVENESS

The subject was introduced by the Commission representative. Member States representatives welcomed the initiative but reminded that prices and reimbursement are sensitive questions. They expressed the view that the Transparency Committee, foreseen in Directive 89/105/EEC, should be revitalised to explore possible steps forward on prices and reimbursement of medicinal products. The Commission representative reminded that if the Transparency Committee is convened, the Member States should make sure that representatives with the necessary expertise on the financial as well as the scientific aspect of the question are attending the meetings. He indicated that an invitation will be sent in the next months on the basis of a reflection paper to be drafted by the Commission.

10. A.O.B.

10.1 Rules of Procedure for the Standing Committee

The Commission representative informed the Committee about new standard rules of procedure adopted by the Commission as a consequence of the new comitology decision (Decision 1999/468/EC). The rules of procedure of the Standing Committees for Human and for Veterinary Medicinal Products have to be adapted accordingly.

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

The Commission representative updated the Committee on the recent progress and in particular on certain workshops to be held in the following weeks on specific issues. The next meeting of the Group will be held in February 2002.

10.3 Export certificates

The Commission representative raised the question whether the Member States see any need to work together on a common format of export certificates based on the WHO format. Written responses would be welcome until mid December 2001.

Two Member States explained that their internal format complies already in principle with the WHO format. One delegation asked for the applicability of the certificate's format to veterinary medicinal products.

10.4 Borderline issues: food supplements, biocides and medical devices

The Commission representative updated the Committee on certain borderline issues. The relevant documents will be made available on the web site of the Pharmaceutical unit soon. One delegation called for clear Community legislation on the borderline between

medicinal products and biocides. The Commission representative informed that consensus has been reached between the responsible Commission services on a number of issues concerning in particular antiseptics.

10.5 Biotech initiative

The Commission representative indicated that a consultation paper on the biotech initiative was posted on DG Enterprise's web site in September for general consultation. The deadline for comments is 23 November. The paper will form the basis of a policy paper on a strategic vision of life sciences and biotechnology up to 2010 and beyond.

10.6 Translations of documents

The Commission representative indicated problems, which had occurred in the past with regard to translations of "soft legislation" documents such as guidelines on GMP. The Commission had received a number of complaints about the quality of the translations and it was clear that there was little point in investing resources to perform this work if the work performed was of little value in practice.

The Member States representatives acknowledged the need to improve the situation and to take a decision on the need for such translations. This decision may however need to be taken at a different level. The Commission was asked to analyse the practice in other technical sectors and to present a written proposal.

10.7 Sales promotion

One delegation raised the issue that a recent Commission proposal for a Regulation concerning sales promotion in the Internal Market (COM(2001) 546 final) might have serious and politically sensitive implications in the field of medicinal products. Article 3 of the proposal states that "Member States … shall not impose a general prohibition on the use or commercial communication of a sales promotion unless required by Community Law".

To the extent that the traditional fixed price system at the retail pharmacy level of many Member States will be covered by Article 3, the proposed regulation will give rise to problems – at least in Member States where the fixed price system is synonymous with a prohibition against discounts to the consumer.

Furthermore, with respect to veterinary medicinal products, where Community law on medicinal products is silent concerning advertising, free samples, discounts, gifts, pecuniary advantages or benefits in kind, hospitality at sales etc., Member States might have problems.

The Commission representative pointed out that the Directive 89/105/EEC might provide an answer to some of the concerns expressed, but agreed to consult the Commission's Legal Service on the questions raised.

10.8 Draft Directive on human tissues and cells

A question was raised regarding the relation between the Review 2001, which aims at including new therapies within the pharmaceutical legislation, on the one hand and the draft Directive on human tissues and cells on the other.

The Commission representative explained that so far there is only a project for the new Directive, but no draft proposal, agreed upon by the Commission services. Concerning the delimitation, the borderline to medical devices containing human tissues is subject to discussions within DG Enterprise at the moment. The legal basis for the new Directive would be Article 152 EC, so that the Directive's objective would not be to improve the Single Market. It would rather be to lay down certain standards for the human tissues where use as starting materials.