EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Consumer goods
Pharmaceuticals

PHARM 516

PHARMACEUTICAL COMMITTEE
SUMMARY RECORD
59th meeting, 2nd December 2005

OPENING

Mr Martin Terberger, Head of the Pharmaceuticals Unit of DG Enterprise and Industry, opened and chaired the meeting.

AGENDA

The draft agenda of the 59th meeting (PHARM 507) was adopted. Upon the request of Member States' representatives or the Commission services, the following issues were added to the agenda under point 7, AOB:

— counterfeit products;

— flu pandemic;

— withdrawal from the market of certain insulins.

1. IMPLEMENTATION REVIEW 2001

a) Implementing measures: oral update on the state of play

➢ Council Regulation amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency

The Commission representative presented the main steps leading to the adoption, on 14 November 2005, of Council Regulation (EC) 1905/2005 amending Regulation (EC) No 297/95 on fees payable to the European Medicines Agency (OJ 23.11.2005, L304/1), and a summary of the main provisions contained in the regulation.

➢ Commission Regulation laying down special financial and administrative provisions for SMEs

The Commission representative presented the state of play regarding adoption of this Commission regulation, and a summary of the main provisions contained therein.

[*The regulation was adopted on 15 December 2005 and published in the Official Journal on 16 December (Commission Regulation (EC) No 2049/2005 of 15 December 2005 laying down, pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council, rules regarding the payment of fees to, and the receipt of administrative*

assistance from, the European Medicines Agency by micro, small and medium-sized enterprises).]

- **Commission Regulation laying down the procedure to adopt the maximum amounts and the conditions and methods for collection of financial penalties imposed by the Commission under Regulation No (EC) 726/2004**

The Committee was updated on progress in the drafting of this Commission regulation. In the last Pharmaceutical Committee meeting, held on 12 September 2005, Member States had been invited to provide any further comments by mid-October. On the basis of these comments, as well as contributions received from stakeholders, the Commission services were finalising a text. To answer some of the points raised by Member States in the September meeting, the Commission services were working in particular on further clarification of the instances were the Community will intervene for the enforcement of Regulation (EC) No 726/2004, and were reflecting on the final amount for the financial penalties. The Commission representatives informed the Committee that it would be consulted once again before tabling the draft to the Standing Committee. The Chairman referred to the very extensive consultation held in the last months and strongly encouraged Member States to raise any outstanding issues during consultation of the Pharmaceutical Committee to pave the way for the adoption of a positive opinion by the Standing Committee.

- **Commission Regulation on the conditional marketing authorisation for medicinal products falling within the scope of Regulation (EC) No 726/2004**

The Commission representative provided a verbal update on the draft regulation on conditional marketing authorisations, including the changes to the draft compared to that discussed at the last Pharmaceutical Committee meeting. Following interventions from some Member States, the Commission clarified the changes to the regulation, particularly on renewal of marketing authorisations, and highlighted the importance of the regulation for any influenza pandemic. It was announced that the draft was currently being translated into the official Community languages and that these texts would be sent to the Member States in about one week. It was announced that the Standing Committee was likely to be held on 16 January. Given the urgent need to have the regulation in place, particularly due to its role in the Community response to the threatened influenza pandemic, the Commission representative asked the members of the Pharmaceutical Committee to indicate whether they foresaw any barriers to adoption by the Standing Committee. The Pharmaceutical Committee did not foresee such barriers and the Commission called on the Member States to support a positive opinion on 16 January.

b) Guidelines: for discussion:

- **Guideline and reflection paper on Article 3(2) of Regulation (EC) No 726/2004 – Optional scope of the centralised procedure**

The Commission representatives introduced this guideline and reflection paper and stressed their importance from the point of view of the operation of the network of competent authorities, since they would impact on the share of work between the Member States and the Community. Following the discussion at the last Pharmaceutical Committee meeting, written comments had been received from three Member States. The

EMEA had produced new drafts where these comments had been partially taken on board. The EMEA representative briefly introduced the main changes to the texts.

It was agreed that the guideline concerning the optional scope of the centralised procedure, in its current form, would be released by the Commission for public consultation. Following the consultation the finalised guideline will be incorporated into Notice to Applicants, Volume 2C.

[The draft guideline was published on the pharmacos web-site on 21 December2005 for comments to be sent by 31 January 2006. The guideline applies to human medicinal products and provides guidance on:
- EMEA procedure for confirmation of eligibility to the centralised procedure;
- definition of new active substance not authorised in the Community, at the time of entry into force of the Regulation;
- justification of significant therapeutic, scientific or technical innovation; and
- eligibility based on interests of patients at Community level.]

There was a detailed discussion on the reflection paper on the notion of "interest of patients at Community level", in particular on the type of criteria that would be most appropriate to determine in which circumstances it is in the interest of patients to obtain a centralised marketing authorisation. Several Member States' representatives considered the draft too wide, especially by including the lack of harmonisation as a criterion giving access to the centralised procedure. It was agreed that the Commission services and the EMEA would work on a revised draft to be sent to the Pharmaceutical Committee for further discussion.

- **Guidelines on the additional year of marketing protection under Article 14(11) of Regulation (EC) No 726/2004 and on the one-year data exclusivity period of Article 10(5) of Directive 2001/83/EC as amended by Directive 2004/27/EC**

The Commission representative briefly presented the two guidelines on different aspects of data exclusivity. Following the discussion of them at the last pharmaceutical committee written comments had been received from Sweden and Ireland. Those from Sweden had been partially taken on board by the EMEA while those from Ireland had not yet been incorporated. The Commission called on the Committee to raise any major issues, particularly with the definition of therapeutic indication but also with any other aspect of the guidance.

Several Member States' representatives made interventions relating to the definitions in the guidelines. These included the view that the definition of therapeutic indication was too restrictive and that the use of the ICD-10 classification for defining a change of therapeutic indication was restrictive, that the importance of viral transmission justified recognition, and that in the context of 'significant clinical benefit' the exclusions were considered too inflexible.

It was agreed that these suggestions, together with those that had been received in writing would be highlighted in a text to introduce a public consultation, conducted by the Commission, of the guideline which would be released in its current form. Following the consultation the finalised guidelines will be incorporated into Notice to Applicants.

c) Transposition of Directive 2004/27/EC by the Member States

The members of the Committee were invited to give a brief update on the state of transposition of Directive 2004/27/EC. According to the Chairman, in spite of certain delays in transposition, the provisions of the new legislation are generally being applied, and the Commission services are aware that most Member States are dealing with transposition as a matter of priority. The Committee was informed that progress will be monitored carefully to ensure that the system put in place by the new legislation is indeed operating.

2. TISSUE ENGINEERING AND ADVANCED THERAPIES

➢ Commission's proposal for a Council and European Parliament Regulation: update on the state of play

The Commission representative presented the main points of the Commission proposal adopted on 16 November 2005. In particular, the main changes to the version of the text discussed in the Pharmaceutical Committee meeting of June 2005 were explained. These include a clarification in the definitions, the inclusion within the scope of products derived from tissues of animal origin and a clear statement concerning the neutrality of the proposal as regards embryonic stem cells.

3. ORPHAN MEDICINAL PRODUCTS

a) Procedure for designation of orphan medicinal products (Article 5(8) of Regulation (EC) No 141/2000)

The competent authorities of the Member States were invited to send to the Commission services an electronic address of contact for the purposes of the application of Article 5(8) of regulation (EC) No 141/2000.

b) Guideline on the review of the orphan status of medicinal products after 5 years of marketing authorisation (Article 8(2) of Regulation (EC) No 141/2000)

The Commission representative informed the Committee of work in progress on a guideline for the application of Article 8(2) of Regulation (EC) No 141/2000, which allows the reduction of the market exclusivity period of Article 8(1) where certain circumstances are met. A public consultation will be held in the first half of 2006 and a draft will be tabled at the next Pharmaceutical Committee meeting for discussion. An expert working group has been set up to work on this draft guideline. It was highlighted that the issue of defining and assessing profitability was a very sensitive point for stakeholders and that a detailed discussion on the interpretation of Article 8(2) is on-going within the Commission services.

4. PHARMACOVIGILANCE

➢ Commission's study "Assessment of the Community System of Pharmacovigilance"

The Commission made a detailed presentation of the Commission study "an Assessment of the Community System of Pharmacovigilance" together with how the Commission proposed to handle the report and next steps. Following the presentation it was made clear that some possible actions were for the Commission while others were for

individual Member States. It was agreed that if individual Member States wanted the data collected on that particular Member State then this could be requested from the Commission (contact Peter Arlett).

The Chairman categorised the identified weaknesses into two groups: 1. those relating to Member State divergences (e.g. in resources or in legislation implementation), and, 2. the handling and actions based on pharmacovigilance data collected.

Several Member State representatives made observations including: highlighting the complexity of the legal provisions for pharmacovigilance, as well as the inconsistencies in the legislation and the practical difficulties with operating the provisions, the need to study the impact of regulatory measures taken, and highlighting the lack of resources available. A factual error in the report was pointed out by one representative although it was clarified that this had already been corrected.

The Committee endorsed the following: the report will be provided to the Member States as a 'confidential draft' and Member States will be invited to comment on matters of fact within two-weeks. The report will then be made public and a public consultation on it will be initiated. The Commission will endeavour to produce a document which responds to the identified weaknesses to help the Member States deal with enquiries. Furthermore, the Heads of Medicines Agencies European Risk Management Strategy Group will be asked to advise. With input from the Pharmacovigilance Working Party, the technical discussions will be channelled through the Pharmaceutical Committee.

5. INTERNATIONAL ASPECTS

➢ ICH: update

The Commission presented an update on the International Conference on Harmonisation (ICH), including an update on the proposed and ongoing technical topics being discussed, the decisions taken at the Steering Committee in Chicago in November 2005, and a "reflections paper" from the US Food and Drug Administration (FDA). The FDA paper has two main objectives: 1. to improve communicating with stakeholders and to increase the impact of ICH guidelines and standards beyond the formal ICH partners. The Chairman explained that the increasing of impact includes consideration of working with international accredited standards organisations for electronic standards, such as the electronic Common Technical Document. The FDA is known to work currently with the organisation Health Level-7 (HL7). The Chairman further explained that Hans-Georg Wagner, Head of Unit at the EMEA, will be the co-rapporteur for the ICH discussions on working with standards organisations and will prepare a paper for a detailed discussion at the May 2006 Telematics Steering Committee. The Commission made clear that, based on the advice received from Member States and the EMEA, the Commission would take an EU position at the ICH Steering Committee in Yokahama in June 2006. This position would determine the conditions for working with standards organisations and the 'rules of engagement'. Written comments on the FDA 'reflections paper' were invited with a deadline of 31 December 2005.

6. PHARMACEUTICAL FORUM: UPDATE ON THE STATE OF PLAY

The Committee was informed of the rationale and objectives of the Pharmaceutical Forum, launched as a continuation of the G-10 activities, the structure that it would adopt (yearly Forum, Steering Committee and working groups) and the selected themes. It was highlighted that the process is intended to involve all Member States and interested

parties, in contrast with the G-10 exercise, and that active participation will be the key to its achievements.

There were some interventions from Member States' representatives on workability issues, avoidance of duplication of work and involvement of other parties, such as DG Research within the Commission.

7. A.O.B.

a) Counterfeit products

The Commission representative informed the Committee of two on-going initiatives in the field of counterfeit products: a seminar organised by the Council of Europe in September with a presentation of the Harper report, which may lead to proposals for a Council of Europe recommendation, resolution or convention; and the WHO concept paper containing a proposal for a framework convention. It was stressed that the WHO proposal for a framework convention demands early coordination with the Member States since it would impact on the Community legislative framework for pharmaceuticals and would demand the adoption or amendment of legislation. The Committee was informed that, although the proposal is tabled for discussion in the conference scheduled for February 2006, the Commission has already informed WHO that detailed discussion is necessary within the EU and that February 2006 is too early to be able to reach agreement on the proposal. Member States showed support for an EU co-ordinated approach in this matter. In order to be able to move forward and adopt an EU position, Member States were requested to send their written comments on the proposal for a framework convention to the Commission services at the beginning of January 2006. During the discussion involvement of the FDA into the WHO discussions and communication between EU and FDA on counterfeit strategies under the EU-US confidentiality agreement was confirmed. In addition, concerns were expressed that the Council of Europe and WHO proposals could go into different directions. This would not be desirable and should be avoided.

b) Flu pandemic

The EMEA and the Commission reported on recent action taken at Community level in preparation of a possible flu pandemic, including the simulation exercise of a flu outbreak involving the Member States, the Commission and other authorities.

c) Withdrawal from the market of certain insulins

A Member State raised the issue of certain recent withdrawals of marketing authorisations for insulins granted through the centralised procedure, and the health problems that this may raise for those patients who could not easily switch to other products. The Commission representative informed the Committee that the Commission has no competence to interfere in the marketing strategies of marketing authorisation holders, and that health care delivery fall under Member State responsibility. It was added that this has been the position recently taken by the Commission in response to a parliamentary question addressed to it[1]. It was agreed that this response would be circulated to the members of the Committee, and that, on the basis of any feedback from them, the Commission services would, if necessary, look into the question again.

[1] See Written Questions E-1804/04, E-1089/04, E-2542 to 2551/05, E-4056/05, and petition N° 1086/2003