EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single market : management & legislation for consumer goods
Pharmaceuticals : regulatory framework and market authorisations

PHARM 478

PHARMACEUTICAL COMMITTEE

Subject : Summary record of the 56th meeting of the Pharmaceutical Committee on 19th January 2004

Action to be taken:

For adoption

PHARMACEUTICAL COMMITTEE
SUMMARY RECORD OF THE 56th MEETING
19th January 2004

OPENING

Mr Paul Weissenberg, Director of Directorate F of DG Enterprise, opened the meeting and chaired the discussions on points 1, 2, 3, 4.c) and 5.

AGENDA

The draft agenda of the 56th meeting (PHARM 467) was adopted.

SUMMARY RECORD

The summary record of the 55th meeting (PHARM 466) on 15th May 2003 was adopted without amendment.

1. LEGISLATIVE ISSUES

a) Review of the pharmaceutical legislation

The Committee was informed of progress in the adoption of the legislative package and on the expected dates for adoption, publication, entry into force and application. There was some discussion on the transitional arrangements until the whole package is in operation.

The Commission representative presented a list of implementing measures to be adopted by the Commission in the coming months. The importance of cooperation between the Member States and the Commission during this period was underlined, and the Member States were invited to inform the Commission on progress in transposition and to consult it if difficulties arise.

The EMEA representative explained that the Agency was already working to prepare for enlargement and for immediate application of Title IV of the new regulation.

b) Paediatric medicines

The Commission representative informed the Committee of the main activities undertaken since the last meeting of the Ad Hoc Working Group dealing with this draft proposal, in particular consultations with stakeholders and launching of the extended impact assessment.

c) Variations Regulations

The Commission representative informed the Committee of the on-going reflection on possible amendments to the variations regulations to take account of the particularities of biological medicinal products.

d) Tissue engineering

The Commission representative updated the Committee on the preparation of the proposal. The draft under preparation builds on previous preparatory work (namely, the 2002 consultation, the IPTS report and the meeting with experts of the Member States in September 2003).

The proposal aims at establishing a specific legal framework for tissue engineered products, separate from that of medicinal products and medical devices. The main challenges relate to the definition of tissue engineered products and its borders with other definitions contained in other pieces of Community legislation.

2. G10

The Committee was updated on the follow up to the Commission's communication adopted in response to the Report of the G10. The implementation of the various actions contained in the Communication will be done, where possible, through existing mechanisms (such as the review of the pharmaceutical legislation or the public health programme). Some areas of action will have to be implemented independently of existing mechanisms, notably:

— Patient information. The implementation of this point will include the setting up of public-private partnerships. To that effect, DG ENTR and DG SANCO are jointly drafting a proposal.

— Benchmarking. DG ENTR is updating the competitiveness indicators published in the Communication. This will be done with the support of Member States as set out in the Council conclusions on the G10 Communication. The exercise will be extended to the new Member States wherever possible. In parallel, DG SANCO is working on a benchmarking exercise concerning public health impact of the pharmaceutical industry.

— Reflection on pricing. A working group will be set up within the framework of the Transparency Committee, made up of representatives of several Commission services, interested Member States and stakeholders, including industry and experts.

— Added therapeutic value. A working group has been set up within the framework of the Transparency Committee. The group is working on a questionnaire which will be submitted first for consideration by the Transparency Committee and then to the Member States for completion.

The Chair invited Member States to work alongside the Commission on these four topics which present considerable challenges.

3. INTERNATIONAL ASPECTS AND ENLARGEMENT

a) ICH

The Commission representative updated the Committee on the ICH Steering Committee and Conference held in Osaka in November 2003.

Discussions took place in the Steering Committee on the future of ICH, and future discussion is planned for the Washington Steering Committee in June 2003. Member States were invited to present their views on this topic. Following discussion, there was broad agreement on the following issues: support for cost benefit analysis before launching new initiatives; need to focus on implementation and maintenance; need to ensure the appropriate role of the non innovative industry in the Steering Committee.

The possibility of discussing on a global basis Internet advertising of prescription medicines was raised by a Member State. The Chair agreed to raise the point in the Washington meeting.

b) Enlargement

The Commission representative informed the Member States of progress in the preparation of a Commission communication on the application of Community legislation on medicinal products in the context of enlargement.

4. INTERPRETATION/IMPLEMENTATION OF LEGISLATION

a) Recent case law

The Commission representative presented the main findings contained in the rulings in the following cases:

— Case C-39/03 P, judgement of 24 July 2003, "Artegodan (anorectics)", on the Commission's competence to adopt decisions in referral procedures;
— Case C-223/01, judgment of 16 October 2003, "AstraZeneca", on the interpretation of Article 10(1)(a)(iii) of Directive 2001/83/EC concerning the conditions for the application of the abridged procedure for the granting of marketing authorisations to generic medicinal products;
— Case C-322/01, judgment of 11 December 2003, "DocMorris", on the compatibility with Community law of national legislation whereby medicinal products for human use the sale of which is restricted to pharmacies in the Member State concerned may not be imported by way of mail order to pharmacies approved in other Member States in response to individual orders placed by consumers over the internet;
— Case T-326/99, judgment of 18 December 2003, "Nancy Fern Olivieri v Commission and EMEA", on the Commission's obligation to examine information brought to its attention in the framework of marketing authorisation procedures and the rights of the persons submitting such information.

There was some discussion on the consequences of the "DocMorris" judgement and the possible need for harmonisation in the area of distribution of medicinal products. The Commission representative noted that such harmonisation was for the time being not envisaged.

A question was raised as to the applicability of the findings of the Court of First Instance in the "Olivieri" judgment in the framework of mutual recognition procedures. The Commission representative replied that there was nothing to prevent applying those principles on the examination of information and rights of third parties in the framework of national procedures for the authorisation of medicinal products.

b) Implementation of Directive 2003/63/EC

The Commission representative informed the Committee of the steps taken to put in place the necessary procedural arrangements for the certification of Vaccine Antigen Master Files (VAMF) and Plasma Master Files (PMF) introduced by Directive 2003/63/EC. Drafts of two guidance documents by the EMEA, to be adopted by the CPMP, were distributed and briefly presented. In addition, the Commission announced its intention to adopt guidance on the "second step" procedure, when the competent authority that has granted or will grant the marketing authorisation will have to take into account the certification, re-certification or variation of the VAMF/PMF on the concerned medicinal product(s). The Committee will be consulted during the drafting of this '2nd step' guidance document.

c) Interpretation of Article 10(1)(a)(ii) of Directive 2001/83/EC: well-established use

An interpretative note by the Commission services on the well-established medicinal use (WEU) procedure was tabled for discussion. The note had been initially drafted as an internal document for distribution within the Commission and EMEA, but it had subsequently also been distributed to the Member States which had asked for a discussion. In essence, the Commission note concluded that the well-established medicinal use procedure is not the adequate legal basis to process mixed dossier applications; rather, the procedure is to be used only in cases where all the contents of the dossier relating to the safety and efficacy of the product are bibliographical. It suggested that mixed dossier applications must be submitted and processed following the standardised marketing authorisation dossier requirements as foreseen in Article 8 (3).

Some Member States considered the Commission's position to be too restrictive by not allowing the use of mixed dossiers under the WEU procedure.

d) Pharmacovigilance

The Commission representative presented to the Committee a Commission initiative for the assessment of the European Community system of pharmacovigilance, with a view to strengthening the system and making it fit for operation in an EU of 25 members. The Commission proposes a comprehensive assessment of all pharmacovigilance processes conducted by the relevant Competent Authorities in the Community, to be conducted during 2004 (subject to the adoption of a decision concerning budget allocation by the Commission).

Discussion followed concerning the opportunity of carrying out the exercise now (in view of enlargement and the completion of the Review 2001 which places now the interest on implementation), and on the need to take stock from existing initiatives (such as discussion in the framework of HoA, the EMEA's risk management strategy and Eudravigilance).

5. NEW FORMAT FOR THE MEETINGS OF THE PHARMACEUTICAL COMMITTEE

The Chair proposed the Committee to hold a discussion on a possible change of the format of the Pharmaceutical Committee. The following guiding principles for such a reformatting were proposed:

— More interactive running of meetings.
— Creation of working groups for the more technical topics, where Member States would be represented by the appropriate experts.
— Organisation of meetings devoted exclusively to a single topic, such as the implementation of the review or enlargement.

Member States agreed to the above points. The following additional points emerged from the comments by the Member States:

— Use of the Committee for the discussion of important policy issues. Need for a clear distinction in the agenda between items for discussion and items for information only.
— Possible joint meetings of the Pharmaceutical Committee and the Veterinary Pharmaceutical Committee.
— More speedy adoption of minutes (written procedure).
— Selection of dates and distribution of documents more in advance.

It was agreed that the Commission would prepare a short paper outlining the main points and invite the member States to comment.

6. MARKETING AUTHORISATION PROCEDURES

a) Mutual recognition procedure

The Italian former Chairperson of the MRFG updated the Committee on recent developments in the mutual recognition procedure. In particular, information was provided on the co-ordination demands resulting from enlargement, the status of harmonisation of SmPCs, the operation of the Joint working group PhVWG/MRFG, GCP and GMP compliance issues, and progress on information sources (adopted documents, MRFG website, Eudratrack).

b) Centralised procedure

The EMEA representative gave an update on the centralised procedure. In particular, information was provided on the working group on patients' information and on certain on-going scientific assessments.

7. A.O.B.

a) Human Pandemic Influenza Initiative

The Committee was updated on the Commission's initiative concerning Human Pandemic Influenza and provided with copies of the draft guidance documents prepared by the EMEA.

b) Creutzfeld-Jakob Disease and Bovine Spongiform Encephalopathy

Following-up on the recent UK case of human Creutzfeld-Jakob disease, the Commission representative informed the Committee of a workshop being held the following week at EMEA on blood derived medicinal products and related TSE/BSE risks. On the basis of the outcome of the workshop, the Commission would reflect on the need for further action.

c) Women in clinical trials

A Member State raised the issue of the need for the appropriate representation of women in clinical trials and invited the Commission to provide guidance in that regard. The Commission representative informed the Committee that the next ICH Steering Committee in Washington would review ICH guidance to determine the areas were reference to gender issues is necessary. In view of the result, there may be need for ICH guidance on the subject. Otherwise, the EMEA will be tasked to draft such guidance, in general terms or for specific products.

d) Priority Medicines

The Dutch representative informed the Committee of the Priority Medicines initiative to be launched under the Dutch Presidency to look at the research and development agenda into very necessary medicinal products. A conference will be held on 18 November 2004.

e) Commission Communication on Parallel Trade

The Committee was informed of the adoption of a Commission communication on parallel imports of medicinal products, prepared by DG MARKT. It was agreed that a copy of the communication would be sent by e-mail to the Member States after the meeting,