PHARMACEUTICAL COMMITTEE
SUMMARY RECORD OF THE 53rd MEETING
14th May 2002

OPENING

Mr Paul Weissenberg, Director of Directorate F of DG Enterprise, opened the meeting and chaired the discussions on points 2.1, 2.3, 5, 6, 7.1, 7.3, 7.4, 9.1, 9.2 and 9.3.

AGENDA

The draft agenda of the 53rd meeting (PHARM 394) was adopted. Following a request by the Netherlands, a new item was added under point 9 (A.O.B.) relating to the distribution of medicinal gases. Agenda points 9.4 and 9.5 were postponed to the next meeting.

SUMMARY RECORD

The summary record of the 52nd meeting on 14th May 2002 (PHARM 395) was adopted with one amendment. On request of the Belgian representative, one sentence was added under point 4 to clarify that the GMP Annex 13 has been updated to take into account Directive 2001/20.

1. INTERPRETATION/IMPLEMENTATION OF LEGISLATION

1.1 Information on recent case law and pending cases

The Commission representative informed the Committee about the recent ECJ judgement of 27 November 2001 in Case C-424/99 on the implementation of Directive 89/105/EEC by Austria. The Austrian representative explained that preparations are far advanced to respond to the court's judgement.

The Committee was also updated on recent developments in the so-called anorectic cases and in particular on the ECJ's order of 14 February 2002 in Case T-74/00. The Member States confirmed that there are no medicinal products containing anorectic substances any more on their markets.

1.2 Implementation of TSE requirements (ex-Directive 1999/82)

The Commission representative recalled that existing marketing authorisations had to comply with the new requirements laid down by former Directive 1999/82 by March 2001. He invited the Member States to update the Commission about the situation in each country by end of June 2002.

The Danish and the British representative gave an oral update on the situation in their countries. Both pointed out that they are still waiting for a number of certificates by the EDQM. The EDQM representative asked the Member States for information about which certificates are needed most urgently in order to prioritise the EDQM's work.

1.3 Directive 2001/20/EC on clinical trials

The Commission representative reported on the progress on implementing texts relating to Directive 2001/20/EC on clinical trials. The texts are either released for consultation already or the release is forthcoming.

1.4 Codification of pharmaceutical legislation

After introduction by the Commission representative, the Member States other than those mentioned in PHARM 400 explained that they do not intend to take specific measures to implement the two Community Codes on medicinal products because of their mere codifying character. The Commission representative invited the Member States to inform the Commission about any translation mistakes they detect in Directive 2001/82 or 2001/83.

2. LEGISLATIVE ISSUES

2.1 Annex I to Directive 2001/83/EC

The Commission representative reminded the Committee that most parts of the proposed changes implement the CTD that has already been discussed within the NtA in detail. The other parts of the proposals are reflecting the provisions of Directive 2001/83 and have been discussed with the Member States to a large extent too. In reply to a question raised by the Dutch representative, the proposals therefore could be adopted by comitology.

The Commission representative explained that 17 June 2002 would be maintained as deadline for comments on the draft since the CTD has to be implemented by 1 July 2003 and the translations of the highly technical document will take a lot of time. But he indicated that late comments could still be considered as far as practically possible. During the next meeting of the Pharmaceutical Committee, the amended text based on the comments received will be discussed in detail.

2.2 Variations regulation

The Committee was updated by the Commission representative on the progress in amending the variation regulations. The NtA has established a drafting group, which has met a couple of times and is going to finalise the proposals until summer 2002. It is envisaged to consult the Standing Committee in autumn 2002.

2.3 Paediatric medicines

The outcome of the recent consultation on the Commission services' reflection paper was outlined. The Member States representatives welcomed the Commission's initiative and the ideas set out in the reflection paper, but called for further discussion on certain aspects like data protection and funding.

The legislative proposal will be drafted by the Commission services shortly. On the basis of this proposal, the Pharmaceutical Committee will be consulted again.

3. MARKETING AUTHORISATION PROCEDURES

3.1 Mutual recognition procedure

The Spanish representative updated the Committee on recent developments related to the MRP and in particular on the ongoing harmonisation of SmPCs. Out of 36 products that have been selected as candidates for harmonisation, first procedures will be launched on 6 products. Currently, co-ordinators are chosen amongst the CPMP members. The Heads of Agencies will decide on the legal basis during their next meeting.

3.2 Centralised procedure

The EMEA representative informed the Committee about recent CPMP activities. The scientific advisory groups have been reinforced. The number of referrals on pharmacovigilance issues is continuously increasing. Certain class referrals have been finalised.

He pointed out that there are also more and more procedures where issues of risk management programmes are at stake. This is particularly true for an application regarding thalidomide. The key problem is how to effectively organise the risk management and its control.

The German representative expressed concern about authorising thalidomide again since the existing mechanisms would not be sufficient to ensure the necessary risk management. The Commission representative highlighted that during the comitology procedure for such an authorisation, the Standing Committee would need to be convoked in order to ensure a detailed discussion with the Member States of such authorisation and its implications.

The EMEA representative told the Committee that the EMEA has been contacted by thalidomide victims who are concerned about the new application. The EMEA intends to hold a meeting with victims' representatives and patient/consumer organisations.

3.3 Notice to Applicants

The Commission representative updated the Committee on recent activities of the NtA. The application form prepared will be updated shortly in accordance with Directive 2001/83/EC and will then be published.

4. GOOD MANUFACTURING PRACTICE

The Commission was informed about the work of the inspectors' group on procedures for exchange of information and for complaints as well as on Annex 7 to the GMP Guide on Herbal Medicinal Products. After various problems, the Member States were reminded the importance to allocate the necessary resources to support inspections requested by the Commission or the EMEA with regard to issues of common interest for the Community.

5. TELEMATICS

5.1 Telematic Strategy

The Commission representative explained that the Telematic Strategy has been developed during 2001. On this basis, the EMEA has drafted a working programme. During the next meeting of the Telematic Steering Committee, necessary adjustments as well as a precise calendar would be discussed. A document describing the respective responsibilities to realise the strategy is currently being prepared.

The EMEA representative added that the overall costs have been estimated to be about € 7 Mio in 2003 and about additional € 5 Mio in 2004 and 2005. There are a number of different elements of the overall IT systems like EudraNet, EudraTrack or the databases on clinical trials and on medicinal products (EudraPharm). Priority lies with those elements which are prescribed by Community legislation and urgently needed like the data base on clinical trials, EudraVigilance or EudraNet. The realisation of other elements might be delayed due to budget constraints.

The Commission representative reminded that the Telematic Strategy has been commonly agreed by Member States, Commission and EMEA and hence should be commonly supported.

5.2 EudraTrack

The Spanish representative informed the Committee that the Heads of Agencies have created a working group in February 2002 with the participation of France, Germany and the Netherlands. The group works on transferring EudraTrack from the JRC to Member State level. Concrete work has already been started to install the system in Spain. The JRC is willing to run EudraTrack until it is taken over by a Member State, even if this should take place later than 2002.

The Commission representative congratulated Spain and the enlarged Troika for the excellent progress achieved.

5.3 EudraVigilance

The EMEA representative confirmed that EudraVigilance is operational for human medicinal products since 5 December 2001 in a basic version. So far, only Portugal is regularly using it. With Italy and Denmark, the necessary tests are almost completed. The tests with industry are still going on. In its next meeting, the EudraVigilance working group will address the issue of a EudraVigilance dictionary.

The Belgian representative underlined the need for a common terminology and stressed that Member States would need updates and support when using EudraVigilance at national level.

The EMEA representative explained that the Telematic Implementation Group EudraPharm is working on the issue of common terminology and that progress has been made. However, the legal and practical requirements need to be analysed in detail before a database could be set up. This analysis is currently delayed due to lack of budget.

6. MEDDRA

The Commission representative gave an update on the current state of the translations. She explained that on the long run translation for the level "lowest-level terms" should be accomplished for all official languages.

7. INTERNATIONAL ASPECTS AND ENLARGEMENT

7.1 ICH

The Committee was informed about recent ICH activities. The adoption of the eCTD is envisaged for September 2003. More information on the practical aspects are available on the ICH web site. A new ICH guideline on the comparability of biological medicinal products is forthcoming. To the contrary, the "E5" guideline that has been discussed for years continues to cause problems.

7.2 MRA

Regarding the MRA with Canada, the Commission representative told the Committee that the operational phase has been referred due to problems with one Member State. The Commission has taken various initiatives and on the basis of a plan, set up with this Member State, major progress has been achieved. To the contrary, the MRA with the USA does not make major progress. By November 2001, the USA should have assessed all Member States, but in practice only the assessment for the UK has been accomplished and that for IRL is almost finished. For the MRA with Switzerland, the final signatures are still awaited.

The Commission representative explained that the effects of situation of the MRAs after accession would require further analysis. Since the MRAs concern various sectors, a horizontal solution would be necessary. The Commission services will clarify this issue until the next Pharmaceutical Committee.

The Danish representative questioned whether the MRA with the USA is a proper use of resources since the progress is very limited. On his question, the Commission representative explained that major problems concern the translation of Member States' legislation into English.

7.3 Enlargement

The Committee was updated on the derogation clauses on parallel imports in the future Accession Treaties. During the negotiation process, a derogation clause on parallel imports similar to that in the Accession Treaties for Spain and Portugal has been accepted. This clause would allow the patent holder to oppose parallel import of the patented product from the new Member State into one of the current Member States. Industry has repeatedly asked to set up mechanisms that oblige the national authorities to inform the patent holder when a parallel import licence is requested for a patented product. Another possibility would be to create a voluntary scheme where the industry submits to the national authorities lists with the products concerned and the national authorities may inform the patent holder without being obliged to do so.

The Member States welcomed the discussion. But the UK representative highlighted that further discussion is needed on the practicalities. The Danish representative opposed any obligatory scheme of information the national authorities.

The Commission representative underlined that the right at stake is of a private law character and that hence it would be up to the patent holder to enforce his rights. In discussing the practicalities, attention should be paid to the fact that unlike in the case of Spain and Portugal the derogation would be of an unlimited validity.

It was agreed that the Commission services of the different Directorates-General would draft a paper to clarify the practicalities and implications of the derogation clause and to discuss this issue again during the next Pharmaceutical Committee.

The Committee was then updated on the progress on PECAs with Hungary and the Czech Republic as well as on the PECA guidance document.

Further information was given on PERF. The concept for a third phase of the programme were described, including the intention to hold smaller regional conferences in different candidate countries rather than one central conference.

7.4 Bilaterals with the FDA

The Commission representative on the recent meeting between the FDA, Commission's Directorate-General Enterprise and the EMEA in April 2002. A number of practical steps have been agreed like co-operating on post-marketing commitments in the context of risk management or exchange of letters on technical matters. It has been agreed to continue the bilaterals, but to focus on key issues like new therapies rather than on technical aspects. The next meeting will be held in the EMEA.

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

The Commission representative updated the Committee on the progress on this subject. An inventory of medicinal products available in the European Union has been prepared. Further stockpiling seems necessary to prepare for a case of emergency. A summary report has been presented to the Commission.

9. A.O.B.

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

The Committee was informed that the final report of the G10 group has recently been presented to Commission's President Prodi. It contains tangible results in form of 14 recommendations covering issues like bench marking, cost-effectiveness and information to patients. To ensure the necessary follow-up, the G10 group will meet in its prior composition once a year. The Commission has promised to present a political answer in 2003. The Member States will be kept informed about the further progress.

9.2 Working Group on information/advertising

After a brief introduction by the Commission representative, it was agreed that the Commission services prepare a brief document for the meeting of 18 July 2002. It was clarified that the Working Group will not discuss issues related to the ongoing revision of the pharmaceutical legislation. On this basis, the Committee agreed to reconvene the Working Group, in particular to consider the G10 recommendation on enhanced information.

9.3 Transparency Committee

In his introduction, the Commission representative informed the Committee that the Transparency Committee would be reconvened. The committee's role is laid down by Directive 89/105 and it should first of all analyse the recent jurisprudence by the ECJ and aspects of practical application of the Directive's provision. But the Committee could also be asked to discuss further topics like those related to cost-effectiveness as referred to by the G10 recommendation.

Mr Weissenberg told that he would chair the meeting of the Transparency Committee that is scheduled for 27 August 2002. He invited the Member States and Candidate Countries to nominate experts, taking into account that they should possess expertise both on the application of Directive 89/105 as well as on aspects of cost-effectiveness. In order to prepare the discussion, the Commission services will draft a brief document.

9.4 Transparency and access to documents

This agenda item has been postponed to the Committee's next meeting.

9.5 Translation of documents

This agenda item has been postponed to the Committee's next meeting.

9.6 Use of medicinal products by sportsmen

A brief introduction was given by the Commission representative of Directorate-General for Education and Culture, who pointed in particular to the labelling of doping substances and to the creation of an early-warning system.

The Member States' reaction showed very different attitudes. The French representative explained that similar initiatives are taken in France, but that further reflection is needed on a number of practical problems. The idea of an early-warning system was in principle welcomed by the Belgian and the Danish representative. To include information on the labelling was however criticised by the Belgian and the Luxembourg representative. The Swedish representative considered doping a credibility problem that should not be dealt with by the pharmaceutical systems, whereas others raised questions about the resource implications of such initiatives.

The Commission representative explained that the discussion will be taken forward after due analysis of the points raised.

9.7 EU Action Plan on Drugs 2000 – 2004

The Commission representative of Directorate-General for Energy and Transport introduced the issue of medicines' impact on the driving ability of road users. He outlined the following action as possible steps forward: classification of medicines according to their impairment effect in three categories, to be carried out by an ad hoc group; introduction of harmonised symbols for all medicinal products which have an impairing effect on driving; detailed information in the package leaflets and the SmPC.

In a brief discussion, Member States in general welcomed the initiative. But it was highlighted that a similar initiative in 1999 had subsequently been abandoned. The proposed classification in three different categories was criticised by one delegation as being unpractical and difficult to administer.

It was agreed that the issue would be referred to the joint CPMP/MRFG Working Group on the harmonisation of SmPC and to the Quality Revision of Documents Group with a view to setting up the aforementioned ad hoc group. The ad hoc group could be established after summer.

The Commission representative of Directorate-General Justice and Home Affairs then introduced the topic of diversion of Ketamine and made suggestions how the control of such diversion could be improved.

The Belgian and the Dutch representative told the Committee that there are a limited number of medicinal products authorised in their countries containing Ketamine.

It was agreed that the Commission services would prepare a questionnaire to collect further information and to come back to this issue during the Committee's next meeting.

9.8 Distribution of medicinal gases

After brief introduction of the issue by the Dutch representative, it was agreed that further analysis is required. This could be done in the context of the EMACOLEX group, either in form of a questionnaire or a discussion. Afterwards, the issue will be reconsidered by the Pharmaceutical Committee.