PHARMACEUTICAL COMMITTEE
Information on the outcome of the 50th Meeting
21-22 September 2000

OPENING

The meeting was opened by Mr. Paul Weissenberg, Director of Directorate F for DG Enterprise. He made the general point that the regulatory environment was changing, and that it would be important for the committee to ask itself whether each proposed piece of legislation necessarily represented the only and best way forward. He also mentioned the work of the Commission in the field of "better regulation", and suggested members of the Committee to consult with national better regulation bodies.

Mr. Weissenberg chaired the meeting for discussions on points 2.4, 2.7, 4.1 and 6.1.

AGENDA

The draft agenda of the 50th meeting (PHARM 309, version 15.09.2000) was adopted. Two new items were added under AOB: Food Supplements, at the request of the Dutch representative, and the implementation of the Transparency Directive, at the request of the Italian representative.

SUMMARY RECORD

The Finnish representative requested to verify the wording concerning the templates for TSE certificates on the web site of the Commission.
The summary record of the 49th meeting (PHARM 310) was adopted without amendment.

1. INTERPRETATION/IMPLEMENTATION OF LEGISLATION

1.1 Information on new Case Law

The last three Orders of the President of the Court of 1st Instance in cases T-74/00, T-137/00 and T-132/00 on anorectic substances (PHARM 313, PHARM 315 and PHARM 316) were tabled for information. The current situation concerning all the anorectic substances, apart from cases T-141/00 “Trenker” and T-147/00 “Servier”, is that the Commission decisions adopted in March 2000 on the withdrawal of the Marketing Authorisations of medicinal products containing anorectics are suspended.

1.2 Information on pending Case Law

Two new cases concerning the annulment of commission decisions were presented for information. Case T-123/ “Karl-Thomae” concerns a Commission decision refusing an application for variation to a marketing authorisation concerning a change to the

name of the product on the basis that a single Community authorisation requires one single name.

Case T-179/00 "Menarini" concerns a Commission decision refusing the use of the logo of the local representative in the Blue Box of a centrally – authorised product. The Commission representative drew the attention of the Committee to the fact that for the purposes of judicial review the Commission Legal Service considers any EMEA decision to be a Commission decision.

1.3 Borderline medicinal products/biocides

The Commission representative informed the Committee of the proposed modification of the biocides directive being led by DG ENV. Clarifications will be made for borderline products. Discussions focused at length on:

- Antiseptics for "medical use" and whether their exclusion from the biocides directive was defensible given their classification as medicinal products in all Member States;
- The need to ensure, in the case of exemptions, that no products were excluded from both the biocides directive and the medicinal products directives.

As soon as a final proposal is available the Committee will be informed.

1.4 Anti – counterfeiting devices.

The Commission representative presented the EFPIA letter (PHARM 311 and PHARM 311a) about use and possible harmonisation of anti-counterfeiting devices.

Debate focused on the need for such devices, and on whether a Community approach was useful or indeed desirable. Provisional agreement on the need to send a strong signal that the Community intended to tackle counterfeiting head-on was reached, and it was agreed to remit the question to the next meeting of the Notice to Applicants working party.

1.5 Electronic mail addresses in the package leaflet

The Commission representative introduced the question of whether companies should be allowed to include electronic contact addresses in package leaflets.

After a discussion it was agreed to allow inclusion of electronic mail addresses which clearly excluded all promotional links.

1.6 Orphan medicinal products

The Commission representative updated the Committee on progress in the implementation of the Regulation, numbers of applications, opinions issued and decisions reached, and initiated a short discussion on a proposed new guideline for article 8 (market exclusivity provisions).

The question of how to deal with two competing applications going through the marketing authorisation process at the same time was discussed. This problem is most likely to arise in the immediate future when there was a queue of applications waiting to be processed.

2. LEGISLATIVE ISSUES

2.1 Plasma Master File (PMF)

The Commission representative introduced a detailed discussion of the proposal for a separate PMF dossier entity. It was important to be sure that the overall policy principles were agreed by the Committee before moving on.

The discussion focused on two questions:

- Whether the PMF needed to be covered by EU legislation setting out specific details;
- Whether the PMF should be pre-evaluated at European level.

While agreement was reached on the first question, where the Commission will prepare a draft proposal for a legislative amendment to the annex of directive 75/318/EEC, it was agreed that the question of evaluation of the PMF and its link with the marketing authorisation file needed further discussion.

2.2 Variation regulations

The Commission representative introduced the subject, citing the great volume of contributions from industry to the discussion on the revision of the current system. The system, and options for changing it, is being thoroughly examined by the Commission services.

The Dutch representative presented his findings to the committee, as set out in a letter sent to the Commission (PHARM 318a), focusing on:

- The overloading of the MRP and centralised systems, especially with Type 1 variations;
- The need for reform;
- Ways of reducing the workload, whilst still retaining a legal basis

The Committee agreed to delegate discussion to the next meeting of the Notice to Applicants working party.

2.3 Transmissible Spongiform Encephalitis (TSE)

The EMEA representative updated the Committee on the discussions at the recent CPMP meeting, in particular with respect to the clarification that milk derivatives should be excluded from the scope of the note for guidance, in certain defined circumstances. The CPMP expected to finalise the revision of the note with immediate effect at its meeting in October.

In the light of comments from the German representative, the Commission stressed the legal force of the note for guidance by virtue of the amendment to Directive 75/318/EEC.

Industry's ability to comply with the directive for products already on the market by March 2001 was questioned, particularly in the light of the small number of certificates issued by the European Pharmacopoeia. It was agreed that the Commission would send a reminder to industry representatives on the basis of these concerns with a view towards reviewing the situation by the end of the year.

In addition, the Commission services would write asking national authorities for state of play assessments, and discuss these at the next meeting of the Committee.

2.4 Traditional and herbal medicinal products

The Commission services representative reported on the issues that had arisen following discussion at working group level. All members of the Committee accepted the need for legislation in this area. The Swedish and Irish delegations highlighted differences in «traditional » medicines across Europe.

All delegations were agreed that whatever system was adopted it would be essential to ensure the provision of adequate patient information – particularly if traditional medicines were to be subject to a different regulatory regime.

The Commission services will provide a draft text mentioning points for discussion in brackets, on the understanding that members will respond well in advance of the next meeting of the Committee.

2.5 Clinical trials

The Commission representative informed the Committee of the recently adopted Council common position. The draft directive was currently undergoing second reading in the Parliament.

2.6 Codification

The Commission representative updated the Committee on progress recently achieved on codification. In response to questions from the Dutch and German representatives, the Commission explained that most comments had been linguistic. Members of the Committee welcomed the two remaining meetings under the French presidency to resolve difficulties. All were agreed that the codification exercise was not intended to introduce any changes of substance to the legislation.

2.7 Starting Materials

The Commission representative presented the questionnaire (PHARM 324) on the legislation concerning GMP in starting materials. There were a number of questions on which the Committee needed to reflect, including the fundamental definition of a

starting material, procedures for inspection, and compliance with ongoing ICH guideline.

Discussion focused on the need to decide whether only active starting materials or all starting materials should be covered and on perceived problems with imported starting materials from third countries.

At the request of the Chairman, all members of the Committee will respond to the questionnaire and reflect with national authorities on the need for legislation in this area and on possible alternative methods of achieving the aim.

3. MARKETING AUTHORISATION PROCEDURES

3.1 Mutual Recognition

The Portuguese and French delegations introduced their report of the main results of the MRFG discussions.

3.2 Centralised Procedure

The EMEA representative introduced a report on the main results of the centralised procedure. He also announced the CPMP-EMEA " transparency" meeting to be organised before the December meeting of the Management Board.

3.3 Notice to Applicants.

The Commission representative presented a brief update on the different chapters of the NTA**.**

4. RATIONAL USE

4.1 Working group on information/ advertising and working group on electronic commerce.

The Commission representative summarised the results of the wide – ranging consultation on advertising and electronic commerce with stakeholders (PHARM 327). There had been a strong response indicating general concern, but almost all sectors noted strategic uncertainty, especially over possible new distribution channels. Despite that, responses ranged from demands for legislation to warnings that any attempt to regulate would be futile.

The Chairman underlined that at present the Commission Services were trying to formulate a clear view, and the Committee was asked to reflect on ways of going forward. Discussion in the Committee then focused on:

- Possible adoption of some sort of « kitemark » for approved websites, although there were clearly practical problems with this;

- The need to develop a common understanding of the differences between "Advertising" and "Information";
- The extent to which it would be possible for the Community to provide approved information.

There was general agreement that a European approach was needed to a problem that was cross-border and cross-media, and that an over-hasty approach would be unlikely to succeed.

The Portuguese delegation will circulate their national position, currently under preparation, to inform wider European discussion.

The Swedish and Belgian representatives will consider how best to take these issues forward during their forthcoming presidencies.

4.2 Doping in Sport

Discussion focused on whether to introduce a package labelling requirement for products that might cause athletes to fail doping tests. Several delegations felt strongly that a harmonised position on this issue was not necessary. The members agreed to return to this question if it became an issue of concern.

5. GOOD MANUFACTURING PRACTICE.

The Commission representative presented a brief report on the activities of the Inspectors' Group.

6. INFORMATION SOCIETY IN THE PHARMACEUTICAL SECTOR

6.1 Report on Telematic Steering Committee meeting, Lisbon, 12.06.00

The Commission representative reported back on the Telematic Steering Committee in June. He updated members on the four groups that had been formed, and invited comments on each area.

Mr. Weissenberg noted the strategic importance of telematics, and thanked the French Presidency for agreeing to host the next meeting of the next Telematic Steering Committee.

6.2 MedDRA

Discussions focused on the proposal to make the use of MedDRA mandatory, the need for translations, current implementation plans and the possibility of training. It was agreed that the mandatory dates for implementation would be noted in the minutes and subsequently included in Volume 9 of the Rules governing medicinal products in the European Union.

As had been previously discussed, the date for use for single case reports received electronically would be January 2002, and for all adverse drug reaction reporting, January 2003. The Commission had investigated the possibility of providing funding for some training activities on a "train the trainer" basis. However the urgency of this was dependent on the readiness of Member States to implement the terminology on a national basis. It was clarified that MedDRA was available free of charge to all regulators and that the MSSO was also obliged to maintain the terminology.

It was noted that work on French, Portuguese, German, Greek and Spanish translations was either underway or was ready to begin. The Belgian representative stressed the need for a Dutch translation before Belgium would be in a position to implement. The Commission stressed the need to see implementation action at a national level. Nominations for training candidates and work with the MSSO on interlanguage consistency were invited by the 15th October.

7. REVIEW 2000

The Commission representative introduced the summary interim report of the audit (PHARM 314). The final version of this report was expected to be ready along with an executive summary by 15th October. No major surprises were expected in the final version.

Discussion focused on how the follow-up action to the report might be carried out, with most members agreed in discussing the principles and scope of the new legislation in advance, before entering into the details of the concrete Commission proposals. Members of the Committee agreed that a discussion paper be prepared by the Commission setting out their thoughts before the next special Committee meeting on 27 November.

8. INTERNATIONAL RELATIONS

8.1 ICH

The Commission representative presented a draft paper on the future of ICH (PHARM 326a), which was currently under discussion with all the ICH partners. It was noted that this took into account discussions at the previous Pharmaceutical Committee, but the need to re-emphasise global co-operation was stressed.

The Dutch representative drew attention to the fact that the ICH guideline on GMP for active ingredients did not appear to have taken into account comments from the herbal group. The inclusion of new topics in ICH discussions needed to be agreed. The future involvement of WHO will depend on WHO forming its own policy views.

The Commission representative asked members of the Committee to nominate participants for San Diego (ICH5, 9-11 November) by 28 October at the latest. Additional comments on the draft future paper were invited as soon as possible.

8.2 MRAs

The Commission representative made an oral report on the MRAs with the U.S., Japan, Canada and Switzerland.

8.3 Enlargement – PERF

- The Committee was informed that additional funding for PERF II had been agreed in principle, thus allowing a programme to be developed. This could be expected to start in November 2000. The proposed programme for PERF II was based on the conclusions reached at the end of PERF I.

- PECAs with Hungary and the Czech republic have been initialled. The 6-month preparatory work period is expected to begin in early 2001.

9. ANY OTHER BUSINESS

Paediatric Medicines

The Commission informed the Committee on the current discussions in the Council for the adoption of a Council resolution on this issue.

Food Supplements

The Dutch representative raised the problem of the definitions contained in the draft directive on food supplements and the borderline between food supplements and medicinal products. In view of the draft directive under discussion in Council and Parliament, the Committee was asked to reflect upon the need for the pharmaceutical legislation to be amended during the review process in order to exclude explicitly food supplements.

Date of next meeting

An exceptional meeting to deal specifically with the 2000 Review was set for 27 November.

The next Committee meeting would take place in the first half of March 2001, the precise date will be confirmed.