PHARMACEUTICAL COMMITTEE
Information on the outcome of the 43rd meeting
11 June 1997

AGENDA
The draft agenda (PHARM 166, version 10.6.97) was adopted.

SUMMARY RECORD
The summary record of the 42nd meeting on 20 February 1997 (PHARM 167) was adopted, subject to the following modifications :
- Under item 4.b, "Starting materials", the sentence "*Member States were invited to reconsider the issue in the Group of Heads of Agencies*" is deleted.
- Under item 7.b.2, "Herbal remedies", the following sentence is added : "*Some Member States pointed out that a specific regulatory framework would be needed to approach the issue. The Commission promised to consider the need for amendments in legislation after obtaining the results of the ongoing study on herbal medicinal products."*

Following questions raised by Member States, the Commission informed the Committee that it had - in line with the Commission's policy of increased transparency - sent out a "public version" of the summary record of the Pharmaceutical Committee meeting to interested parties after the last meeting. Member States welcomed this approach. However, they expressed concern that the selection of "interested parties" should be well balanced, that Member States should be informed some days before the public and that there should be no substantial discrepancy between the authentic and the "public" version of the minutes. The Commission confirmed its intention to make the information available to all interested parties including consumers' associations (possibly - in future - on the Internet). Moreover the Commission assured Member States that they would always be informed first and that there would be no discrepancy between the two versions (the public version being a copy of the authentic version with internal/confidential information removed)

1. IMPLEMENTATION/INTERPRETATION OF LEGISLATION

a) Commission Communication arising from the second "Bangemann-Hearing" on the marketing authorisation systems
The Commission presented a copy of its draft paper (PHARM 179) on the mutual recognition procedure which had already been distributed and discussed at the Notice to Applicants meeting on 3. and 4. June 1997. Member States expressed their satisfaction with the Commission proposal. There was, however, agreement that further discussion on some items would be necessary. A contribution of the European Generics Association (EGA) on the issue was tabled as a "last minute item" and the Commission asked Member States to consider both this contribution and unresolved problems in the forthcoming Ad hoc Mutual Recognition meeting on 24.6.97. A liaison with industry would also take place. The Commission announced that the above paper would be a cornerstone of the section on mutual recognition of the planned Commission Communication arising from the second "Bangemann-Hearing" on the marketing

authorisation systems. It was also stressed that the Communication was not limited to the issue of mutual recognition. The Commission promised to keep Member States informed of further developments.

b) Colouring matters

The Commission presented its interpretation of Directive 78/25 as outlined in PHARM 170 according to which "colours permitted for certain uses only" would not be allowed for use in medicinal products. Some Member States expressed their concern that this would exclude a number of colouring matters presently allowed under their national legislation. Given that the Legal Service of the Commission had already approved the above interpretation, the Commission alerted Member States that a change of their national legislation in this field might indeed be necessary. Written comments on the issue were invited and the Commission promised to produce a clear legal statement (possibly in the abovementioned Communication - see item 1.a) afterwards.

c) Borderline between medical devices and medicinal products

The Commission orally informed the Committee about ongoing activities concerning the classification of products at the borderline between medical devices and medicinal products. It was announced that the original draft Guideline, MEDDEV 14/95, would be recirculated to the members of the Committee although one meeting had already taken place on a revision of the Guideline. A second meeting was planned (July 1997) when the Guideline would be concluded.

However, since the borderline was difficult to determine in some (small number of) cases, and particularly for new, emerging technology, it was considered that the borderline guideline should be reinforced legally. One possibility would be to use the provisions of the Medical Devices Directive and adopt the resulting classification as a Commission Decision. Further, some preliminary consideration of a procedure for on-going updates of the borderline was explained - although no final proposal was available. For future meetings of the joint Working Party, provision for greater involvement of pharmaceutical expertise would be arranged. The item would also be discussed again at the next Pharmaceutical Committee.

d) CFC's in medicinal products

The Commission had sent out a draft approach to fulfil international obligations under the Montreal-Protocol (PHARM 172). Taking account of comments received (annex to PHARM 172) the draft was revised and - in its revised form - presented to the Committee. The Committee discussed some key problems of the issue (use of Article 12 procedure; production for export to third countries; procedure to authorise the CFC-free substitute (variation or new marketing authorisation)) but did not yet envisage final solutions. Whilst some Member States and the Commission representative from DG XI (environment) stressed the legal and moral obligation of the EU to quickly and significantly reduce CFC-output, other Member States emphasised the need to protect public health (in the absence of technically feasible alternatives) and the concerned sectors of industry. The Commission asked Member States for written comments on the revised draft by 1.7.1997. These comments would be integrated in a new text in a DG XI drafting group meeting on 16.7.1997 and a draft approach for the Community would be presented at an international meeting in September.

2. LEGISLATIVE PROPOSALS

a) Codification; Fees payable to the EMEA

The Commission informed the Committee that the codified pharmaceutical legislation would be translated during summer and autumn and that it could be expected that the texts would be presented to Council and European Parliament (under the simplified procedure foreseen for codification) in January/February 1998.
Regarding the proposed amendment to the Fees Regulation, the Commission expressed its hope that it would be possible to send out a proposal for consultation in July.

b) Starting materials/inspection

The Commission informed the Committee of the content of draft 4 (PHARM 176) of an amendment to Directive 75/319 and of relevant comments received (PHARM 176, annex). Following questions posed by Member States, the Commission confirmed that the new legislation would cover all active ingredients and some excipients (those listed in an annex). The Commission also stressed that the introduction of "Community inspections" should by no means downgrade national inspections and that one of the main features of the new system would be its voluntary character. Concerning the planned GMP certificate, the Commission clarified that this "official document" (which would also be entered into a central database) would serve two aims: to help producers of finished medicinal products to fulfil their obligation under Article 19g of the draft (to only use starting materials manufactured in compliance with GMP) and to help competent authorities in obtaining current information on the inspection status of manufacturers of starting materials or of medicinal products.
Member States cautiously welcomed the proposal and requested the Commission to elaborate the annex and an explanatory memorandum before sending out the text for official consultation. The Commission promised to do so and to send out a technically corrected version of the draft plus annex and explanatory memorandum this summer.

c) Transmissible Spongiform Encephalitis (TSE)

The Commission informed the Committee that it had significantly changed the draft amendment of Directive 75/318 in respect of TSE (which was presented at the last meeting in February 1997 as PHARM 164 corr.), taking into account both the concerns of Member States and industry and other horizontal EU activities on BSE. The new draft (PHARM 177) was presented to Member States which - whilst stressing the need to carefully examine the text - cautiously welcomed the proposal. The Commission announced that the draft would be formally adopted by the Commission shortly and subsequently forwarded to the Standing Committee which would be convened for that purpose in summer 1997.

d) 'Good Clinical Practice in the conduct of clinical trials' and 'Orphan medicinal products'

The Commission informed the Committee that the proposal for a Directive on 'Good Clinical Practice in the conduct of clinical trials' would be adopted by the Commission in July 1997 and subsequently submitted to Council and European Parliament. In parallel, an ad-hoc working group had started its work in order to prepare the draft guidelines which were necessary to complement the text of the Directive.
Regarding the Regulation on 'Orphan medicinal products' the Committee was informed that the draft proposal was being developed i.e. an explanatory memorandum and

necessary “fiches” were being prepared. It was expected to be adopted by the Commission in October 1997.

3. RATIONAL USE OF DRUGS

a) The Guideline on the **excipients in the label and package leaflet** of medicinal products for human use (PHARM 174) was approved, subject to the condition that the date of entry into force of the Guideline would be made more explicit.

b) Although some Member States expressed doubts concerning the draft guideline on **changing the classification for the supply** of a medicinal product for human use (PHARM 175), the Committee took note that the draft would be sent out for consultation.

c) The Commission informed Member States that the **Commission Report on the application of Directive 92/26** (PHARM 171) would be adopted by the Commission and forwarded to the Council in its present form. Some Member States raised the necessity for technical corrections of the text on the one hand and the need for a more intensive debate on legal status and Community law in general on the other. The Commission made clear that the adoption of the report would not be the final point of on-going discussions on the issue. Denmark offered to present a background paper on the “legal status of legal status” in the Community for discussion at the next Pharmaceutical Committee and the Commission accepted this offer.

4. GOOD MANUFACTURING PRACTICE AND INSPECTION

The Summary Report of the Inspectors Working Group meeting of 17 April (PHARM 184) was made available to the Members of the Pharmaceutical Committee for information.

5. MARKETING AUTHORISATION PROCEDURES

a) Mutual recognition

1. Oral Status Report (NL)

(not covered owing to lack of time)

2. Herbal remedies, information on ongoing activities

The Commission informed the Committee that a first meeting of an ad-hoc working group on herbal medicinal products had taken place at the EMEA in London on 9.-10.6.1997 and that two further meetings were planned for this year. The Commission assured the Committee that it would constantly inform its Members of the activities of this ad-hoc group. It was also confirmed that the activities of this group would focus on scientific questions and that a possible need for amendments in legislation would be considered in a separate Commission working party.

3. Mutual recognition of generic products

(was covered under item 1.a)

b) Centralised procedure

1. Status Report.

(not covered owing to lack of time)

2. The Committee was informed of the final version of the **Guideline on the packaging information of medicinal products for human use** authorized by the Community (PHARM 173) and the Commission announced that the text of the Guideline would be incorporated into the ‘Notice to Applicants’.

3. With regard to the future **mandate of the EMEA ad hoc Working Group on Quality Review** of Documents (PHARM 169), some Member States expressed their concern that

this group should not embark on regulatory issues and the interpretation of legislation. The Commission stressed that under Regulation 2309/93/EEC and Directive 75/319/EEC the CPMP had to fulfil clear obligations with regard to the quality and completeness of its opinions. The main aim of the group should therefore be to assist the CPMP in fulfilling this task. Both Member States and the Commission agreed that such mandate should be clearly spelled out in order to prevent misunderstanding and the Commission undertook to clarify the issue in co-operation with the EMEA.

4. Sampling and testing of products covered by the centralised procedure (PHARM 178) The Committee was informed of a proposal for a procedure for the sampling and testing of products covered by the centralised procedure which will operate for a trial period of 12 months commencing in September 1997.

c) rDNA - manufacturing changes

A paper produced by the pharmaceutical industry which had already been tabled at the last (42nd) Pharmaceutical Committee (PHARM 149) was distributed for renewed discussion. The Commission orally outlined possibel solutions to the issue and pointed out that neither industry nor Member States had - so far - informed the Commission on actual cases of rDNA manufacturing changes as required by legislation. Member States were therefore invited to provide the Commission with quantitative information as soon as possible. The Commission would subsequently prepare a document and send it out for consultation.

d) Notice to Applicants

1. Report of meeting in February and June 1997.
2. Vol. IIa (status report)

(not covered owing to lack of time)

6. INTERNATIONAL RELATIONS

a) ICH

The Commission informed the Committee of the countdown to ICH 4 and of discussions concerning the future of ICH. A background document and a strategy paper (PHARM 182) were tabled. The Commission particularly raised the point that ICH and especially the development of a “Common Technical Document” had been given highest political priority and that this topic (on the basis of the feasibility study conducted by EFPIA) would be accepted as an ICH topic for phase 2 of ICH. A streamlined and efficient management would be adopted so that the resource implications for Member States would be minimised. The continued co-operation and input from Member States was requested for this important work.

b) Relations with 3rd countries

Mutual recognition agreements - progress report on negotiations with USA, Canada, Switzerland, Australia, New Zealand, Japan

(not covered owing to lack of time)

c) European Economic Area (EEA)

Information on ongoing activities (extension of the EEA-acquis in the pharmaceutical field) - (not covered owing to lack of time)

d) Central and Eastern European Countries (CEEC)

Unilateral recognition of Community marketing authorizations

(not covered owing to lack of time)

7. A.O.B.

a) A corrected list of members of the Pharmaceutical Committee (PHARM 168) had been distributed for final verification and correction.

b) Internet selling of medicinal products (PHARM 180) - (not covered owing to lack of time)

c) The Committee was informed of a 'Discussion paper on addition of vitamins and minerals to foods and food supplements' (PHARM 181).

d) The Committee was informed of a pilot co-operation procedure between EMEA and the Commission with regard to notifications received under Directive 83/189 (PHARM 183)

e) The Committee was informed of a Commission Communication concerning a programme of Community action on rare diseases within the framework for action in the field of public health (COM(97)225final) and on the control of new synthetic drugs (designer drugs) (COM(97)249final) - tabled for information.

f) It was agreed that a 2-day meeting would be required in order to consider the wide array of important issues. Therefore the **next meeting was provisionally fixed for the 16.-17.9.1997 (two days)** - subject to further confirmation.