PHARMACEUTICAL COMMITTEE
INFORMATION ON THE OUTCOME OF THE 47th MEETING
15-16 April 1999

AGENDA
The draft agenda of the 47th meeting (PHARM 235final - 14.4.99) was adopted. Following requests from the Netherlands and Portugal, two additional items (Pack sizes in the SPCs of MRP products and the issue of "duplicate applications" in the MRP) were added to the agenda as points 3.a.3 and 3.a.4.

SUMMARY RECORD
The summary record of the 46th meeting on 23-24 September 1998 (PHARM 236) was adopted, subject to the following amendment:
Under item 1.c "Interpretation of Article 11 of Directive 92/28", at the end of the paragraph, the following sentence is added: *"It was also agreed that this issue was closely linked to differences concerning the timing of the actual placing on the market of centrally authorised products in different MS and the Commission representative announced to look further into this issue."*

1. INTERPRETATION/IMPLEMENTATION OF LEGISLATION

a) Borderline: information/advertising
The Commission representative stressed the fact that the publication of information about medicinal products is a particularly sensitive activity and that the borderline between "legal information" and – possibly - "illegal advertising" is sometimes hard to draw. In times of the "Information Society", this question would become more and more important and relevant for both the public and economic operators. Based on existing Community legislation (particularly Directive 92/28/EEC on the advertising of medicinal products) a draft interpretative Guidance (PHARM 250) on this issue was suggested by the Commission representative. After having obtained a very positive feedback and having incorporated several constructive remarks from Members of the Committee it was possible to reach agreement on the following revised interpretative Guidance (PHARM 250a):

"*The unmodified and unabridged publication on the Internet of information on medicinal products (prescription only and OTC products) which has been authorised by competent authorities, e.g.:*
- the Summary of Product Characteristics of a medicinal product
- the package leaflet of a medicinal product
- public assessment reports of a medicinal product
should normally not be considered as advertising, unless the presentation of this information clearly constitutes a "hidden inducement" to promote the prescription, supply, sale or consumption of the medicinal product. The existence/non-existence of a "hidden inducement" must be checked on a case-by-case basis, taking into account the overall presentation of the information.

The above principle applies equally to the publication of compendia of Summary of Product Characteristics, package leaflets or public assessment reports in printed form.

According to Article 1 paragraph 4 of Directive 92/28 "correspondence needed to answer a specific question about a particular medicinal product" must not be considered as advertising. "Correspondence" within the meaning of this paragraph should be interpreted to cover also the exchange of electronic messages. Correspondence must, however, be limited to the elements which are necessary to answer a specific question. Unsolicited correspondence (in any form like e-mail, letter, fax, ...) does not fall under the above exception and may constitute illegal advertising"

The Commission representative stressed that the acceptance of this common understanding was a first step which covered only parts of the existing problems. He suggested that a Working Party should be set up to further consider the issue of information on medicinal products and the possible need to amend Directive 92/28. This Working Group should also involve active participation of representatives of patient-, physician- and consumer- associations. The Committee agreed with this proposal.

b) Interpretation of Article 11 of Directive 92/28

Following a request from France, the Commission Services had asked its Legal Service to answer two questions concerning the Interpretation of Article 11 of Directive 92/28 :

- Does "*smallest presentation on the market*" mean the smallest pack which is authorized or the smallest pack which is actually placed on the market (of a given Member State)?
- If a centrally authorised product is placed on the market in some Member States only, can free samples also be provided to persons qualified to prescribe them in other Member States (where the product has not yet been placed on the market)?

The Legal Service of the European Commission gave the following answer (PHARM 248) to the above questions:

"*In the view of the Legal Service the concept "on the market" seems to require that the medicinal product is not just approved by a market authorisation, but that the product is actually in trade, i.e. the product is available to the patients. This interpretation is supported in particular by the French and the German language version of the Directive.*

As to the second question, the Legal Service is most inclined to believe that "on the market" refers to the market of each Member State and not to the Community market as a whole. The provision on advertising of medicinal products are laid down in a Council Directive. According to Article 189 EEC a Directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and measures. The directive has thus to be transposed into national law (opposed to the rules contained in a Regulation). As a general rule, the Member States do only have power to legislate with regard to their own territory. Under these circumstances, the implementation of the directive in each Member State would therefore entail that "on the market" could only refer to the territory of each Member State. This interpretation is also supported by the power given to the Member States by Article 11(2) according to which the Member States may impose further restrictions on the distribution of samples of certain medicinal products. This derogation seems to imply that the Member States may introduce rules different from the Directive in their territory."

The Committee took note of these answers and the French representative expressed his satisfaction with the interpretation given.

c) Judgement of the European Court of Justice of 3 December 1998 in Case 368/96 ("Generics") and of 21 January 1999 in Case 120/97 ("Upjohn")

The text of the above judgements (PHARM 237) were tabled for information. The "Generics" judgement evoked an intensive discussion. Some Members of the Committee welcomed the clear answer given by the ECJ in this case and all Members agreed on the need to have a harmonised common understanding on the practical implications of this judgement. One Member State gave the following specific example:

"...Say a certain medicinal product (20mg tablets) was authorised 12 years ago. Later the following line extensions were approved: 10mg tablets (8 years ago), 20mg

suppositories (6 years ago), 10mg powder for injection (4 years ago). It is our understanding that a second applicant may apply now for a MA for all the line extension products based on Article 4.8(a)(iii) of Directive 65/65/EEC under the condition that he provides proof that his products are essentially similar to the corresponding products of the first applicant and that also the SmPCs of the corresponding products are similar."

The Commission representative and nearly all Members of the Committee agreed with this understanding. The Commission representative reminded the Committee of the fact that the ECJ had clearly expressed the position that: "*A medicinal product that is essentially similar to a product which has been authorised for not less than 6 or 10 years and is marketed in the Member State for which the application is made may be authorised, under the abridged procedure provided for in Article 4.8(a)(iii) of Directive 65/65, as amended, for all therapeutic indications (... and) for all dosage forms, doses and dosage schedules already authorised for that product.*" He also pointed out that whilst it was necessary to demonstrate essential similarity to the corresponding products in each Member State, this did not automatically imply that the SmPCs of the concerned products needed to be identical in each Member State.

The Committee agreed that changes to the position of the ECJ could only be brought about through a change of legislation and that the upcoming 2000/2001-Review of the new marketing authorisation procedures would be an appropriate occasion to consider the issue of possible policy changes in this field.

d) Co-operation between national competent authorities, parallel import of vaccines (PHARM 241)

The Commission representative reminded the Members of the Committee that the following obligation arises directly from Article 5 and Article 30 of the EC Treaty:

The authorities responsible for official batch release (Article 4.3 of Council Directive 89/342/EEC) should communicate with each other when necessary to verify if a batch of a parallel imported vaccine has been officially released by another authority, because the parallel importer will not necessarily have the relevant official batch release documentation.

The Committee took note of this obligation.

e) Borderline medicinal products – other products

Medicinal Gases: The Commission representative presented an updated set of information concerning the status of medicinal gases (PHARM 249) to the Committee and announced that the EMEA Quality WP was going to establish specific Guidance in this sector. The Committee took note of these explanations.

Biocides: The Commission representative circulated a questionnaire concerning the current qualification of non-systematic skin disinfectants in Member States (PHARM 252) and announced that after having received the answers, a harmonised Community approach on this issue would be proposed.

f) Public access

The Danish representative presented the results of a questionnaire on public access, performed by DK within the context of the EMACOLEX group (PHARM 243) and summed up that regulations in Member States on public access were both very divergent and quite restrictive. The Commission representative thanked DK for this precious piece of work and regretted the fact that most Member States had a restrictive approach. He stressed that one should encourage more transparency and expressed the view that there was a justified interest of the public and patients to know, for instance, if applications have been lodged and why applications have been withdrawn. He added that there might be a case for a future legislative initiative of the Community on this issue. Member States announced that they would welcome a Commission initiative.

g) Data Privacy

The Commission representative presented an information note concerning the implications of the Data Protection Directive (Directive 95/46/EC) for the pharmaceutical sector (PHARM 257) and announced that formal letters on this issue would be sent out from DG III to Member States shortly. A representative from DG XV (the Commission DG in charge of Directive 95/46/EC) also announced that interpretative Guidance on frequently asked questions concerning Directive 95/46/EC would be prepared and made available shortly.

2. LEGISLATIVE ISSUES

a) Starting materials

The Commission representative informed the Committee about the content of the updated draft proposal for a EP and Council Directive on GMP for starting materials and inspection of manufacturers – as revised - following the Opinion of the Scientific Committee on Medicinal Products and Medical Devices (PHARM 245). As this proposal was considered to be a "new political initiative", it would be up to the newly appointed Commission to adopt the draft proposal. Therefore it was not expected that the draft could be forwarded to EP and Council before autumn 1999.

Some Members of the Committee expressed concern about the scope of application of the planned Directive and questioned the feasibility of implementing GMP requirements for all excipients. Other members asked, whether the draft would not foresee an unjustified differentiation between EU-produced and imported starting materials. The Commission representative stressed that the Directive would provide a legal frame only and that a differentiated approach with regard to different categories of starting materials would be made possible when adopting the technical Commission Directives and Guidelines foreseen in the draft. On the second point he replied that a European Regulation could of course not impose EU-rules all over the world, but that the EU marketing authorisation holder was in any case responsible that all starting materials used (EU-manufactured or imported) would comply with the requirements of GMP for starting materials.

b) Transmissible Spongiform Encephalitis (TSE)

The Commission representative updated the Committee on recent developments: The Committee for Proprietary Medicinal Products (CPMP) is currently updating – in close co-operation with the Scientific Committees of DG XXIV - a Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products. This Note for Guidance will probably be adopted in April/May 1999. DG III intends to propose to amend the Annex to Directive 75/318/EEC (as soon as the EMEA Note for Guidance will be finalised) to expressly make compliance with the above Note for Guidance binding with regard to all marketing authorisations for medicinal products and to provide for an appropriate phasing-in period for already existing marketing authorisations. It will be proposed to insert a new "paragraph C.a" in Part 2 of the Annex to Directive 75/318/EEC, obliging the applicant to demonstrate that the medicinal product is manufactured in accordance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products, published by the European Commission in Volume 3 of its publication "The rules governing medicinal products in the European Union. A draft proposal (PHARM 261) was tabled for information. It was announced that such draft could be submitted to the Standing Committee for adoption during this summer and that a parallel Directive was planned regarding veterinary medicinal products.

The EMEA-representative presented suggestions from the EMEA/CPMP (PHARM 259) concerning the implementation and the checking of compliance with this Directive. The Commission representative encouraged the CPMP to decide independently about the

most appropriate way forward and promised to answer to the EMEA suggestions in writing. In this context members of the Committee stressed that the importation of finished medicinal products from third countries should deserve particular attention and careful handling. Both the EMEA and the Commission representative promised to follow up this issue.

c) "Well established medicinal use" - proposed amendment to modify the Annex of Directive 75/318

The Commission representative presented a draft proposed amendment of the Annex of Directive 75/318 (PHARM 238). The draft foresees to insert two – parallely drafted - sections "I" on "well established medicinal use" in part 3 (safety) and Part 4 (efficacy) of the Annex of Directive 75/318. He underlined that the proposal aimed to achieve several objectives:

1. to align Community law with current administrative practice in the majority of Member States
2. to clarify that "*bibliographic reference*" to other sources of evidence (postmarketing studies, epidemiological studies, studies conducted with similar products...) and not just tests and trials may serve as a valid proof of safety and efficacy of a product if an applicant explains and justifies the use of these sources of information satisfactorily.
3. to lay down a common understanding of the conditions for "*bibliographical applications*" and in particular the meaning of "well established use" within the meaning of Article 4(8) a (ii) of *"Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products"*.
4. To help solving the practical problems several Member States are facing concerning the re-authorisation of old medicinal products .
5. To give an appropriate follow up to the study carried out in 1998 by AESGP on behalf of the European Commission on herbal medicinal products in Europe. (The main finding of this study was that with regard to the granting of marketing authorisations for herbal medicinal products, legislative clarifications concerning the conditions for "*bibliographical applications*" were necessary.)

Members of the Committee gave a very positive reception to the proposal. Some Members suggested to go even further and to propose – in addition – specific measure for "traditional" medicinal products (a category of products indicated for minor disorders where the proof of efficacy might be replaced by the proof of "traditional use"). The Commission representative underlined that the current proposal had to be seen as a step 1 which could already sort out a number of existing problems and that – as a step 2 – more specific measures concerning traditional medicinal products would be considered – if this was the wish of the Committee. In this context the Commission representative stressed the need to have a close look at the legal basis and to see how far it was possible to proceed with such a second step by means of a Commission Directive. The Commission representative invited written comments on the current proposal to be sent to DG III within three weeks. He promised that the draft would be amended, taking into account these comments and that explanatory remarks/recitals would be added. He announced that the draft would be submitted to interservice-consultation (including a check by the Legal Service of the Commission on the legal basis) afterwards and concluded that – under a best-case scenario – it would be possible to submit it to the Standing Committee for approval this summer.

It was suggested that possible future work on "Step 2" might be discussed at the occasion of the next Pharmaceutical Committee in September 1999.

d) Draft proposal for changing chapter Va of Directive 75/319 (pharmacovigilance)
The Commission representative presented a draft proposal for changing chapter Va of Directive 75/319 (pharmacovigilance) (PHARM 258). Members of the Committee expressed concern about the legal basis for the proposal and the lack of explanatory remarks. The Commission representative took note of these remarks and invited written comments within 3 weeks. He announced that explanatory remarks/recitals would be added to the draft and that subsequent meetings at expert level would further consider the text. In addition, he indicated that comments from interested parties would be requested and that the Pharmaceutical Committee would be kept informed.

e) 'Good Clinical Practice in the conduct of clinical trials' and 'Orphan medicinal products' – Update
The Commission representative informed the Committee that the demissioned Commission was in a position to continue taking decisions on these two drafts because – contrary to the proposal on starting materials - they were not considered as being "new political initiatives". Regarding the Good Clinical Practice draft, the Commission was currently adopting an amended proposal and hope was expressed that work in Council could be continued shortly (possibly still under the German presidency). Concerning the Orphan Medicinal Products draft, it was reported that the Commission was currently working on an amended proposal which could be available by the beginning of May. Possibly a common position could be agreed in Council before July 1999.

f) Codification
The Commission representative made known that the final draft of the Codification would be transferred from the Commission to Council and EP within the next weeks.

3.MARKETING AUTHORISATION PROCEDURES

1. Audit - new marketing authorisation procedures; terms of reference
The Commission representative informed the Committee about the content of the terms of reference concerning the audit on the new marketing authorisation procedures (PHARM 260). The Committee took note of this information. One Member of the Committee questioned the usefulness of having the issue of cost-effectiveness included in the terms of reference.

2. OMCL Guidelines on batch release for biologicals in the EU/EEA
The Council of Europe representative presented a compilation of OMCL Guidelines on batch release for biologicals in the EU/EEA (PHARM 253) to the Committee. The Committee approved the document and the Commission representative announced that the Guidelines would be made available in Volume 3 of "the rules governing medicinal products in the EU" under the double heading of the European Commission and the Council of Europe

3. Harmonised abbreviations for vaccines, Council of Europe – OMCL paper
The European Commission and the Council of Europe representative presented a paper concerning harmonised abbreviations for vaccines (PHARM 239) to the Committee. The Committee, whilst appreciating the need and utility to agree on harmonised abbreviations for vaccines, could not agree on the OMCL proposal. Several members suggested that harmonisation should be agreed first and foremost at an international level before taking unilateral EU steps which might diverge from the US (or other) approaches. The Council

of Europe was therefore asked to look for a consensus on this issue at WHO level and to report to the Committee about further progress.

a) Mutual recognition

1. Oral Status Report (D):

The German representative expressed his satisfaction with the operation of the MR-system. After some problems of interpretation of legislation have been sorted out (partly thanks to the July 1998 Commission Communication) and due to the considerable efforts of Member States in the MRFG to find common and feasible solutions to practical problems, the operation of the MR-system had become smoother. One of the still existing main problems in the operation of the MR-procedure was the tendency of applicants to prefer withdrawals to arbitration.

Following the status report from Germany, the role of the MRFG (legal basis, nature of the documents produced by the MRFG) was intensively discussed. It was concluded that the MRFG (like the Group of Heads of Agencies) did not have and did not necessarily need a legal basis: it currently constitutes an informal co-operation of representatives of Member States who try to find common solutions to practical problems. The papers adopted by the MRFG are adopted by consensus and Member States bear full responsibility for their content. The Commission representative suggested that one might think about the usefulness of integrating the comments made by the MRFG – if they are in line with the Commission's view - into the Notice to Applicants. The merits of having a clearer and legally defined role of the MRFG in European legislation might be considered in the course of the 2001-review.

2. Herbal medicinal products: The final report of a study carried out by AESGP (the full text of this study is available at DG III E 3s website: dg3.eudra.org) and the report from the ad hoc working Group on Herbal Medicinal Products 1997/1998 (PHARM 240) had been sent out to the members of the Committee for information. The Commission representative highlighted that the results of the study had already partly been taken up, when preparing the draft discussed under item 2.c and that further work on a possible Directive on "traditional" medicines would be considered. The EMEA-representative informed the Committee about the work done so far by the ad hoc working Group on Herbal Medicinal Products and highlighted the fact that the mandate of the group had been prolonged by the EMEA Management Board. Members of the Committee expressed their satisfaction about the work done by the Group so far and a lot of divergent views concerning the future role of the Group were expressed. While some Members were in favour of making the herbals working group a subcommittee of the CPMP, other Members expressed concern that – as long as pharmaceutical legislation was not changed to take into account the specificities of herbal products (steps 1 and 2 discussed under item 2.c) – the CPMP might be reluctant to fully appreciate all aspects of the work done by this group. Some members also stressed that the current structure of the Group has worked well. It was therefore agreed by the Committee and accepted by the EMEA-representative to temporarily keep the Group as an EMEA-Working Group "sui generis" which would report regularly to the EMEA/CPMP and to the Commission. Concerning proposals for regulatory Guidance produced by this Group, the CPMP and the Commission would always be consulted in advance and would have a right to rise objections. The mandate of the Group would be reviewed if circumstances changed.

3. Pack Sizes in the SPCs of MRP products:

Following a request from the Netherlands, it was discussed whether it would be permissible to have different pack sizes authorised in different MS for products having undergone the MRP. The Commission representative stressed that according to chapter III of Directive 75/319, the mutual recognition of marketing authorizations for medicinal products is based on the principle that the Summaries of the Product Characteristics

(SPCs) for products having undergone the mutual recognition procedure shall be identical and remain identical in all concerned Member States. Point 6.4 of Article 4a of Directive 65/65 explicitly mentions the "nature and contents of containers", i.e. the pack sizes, as an integral part of the SPC. Therefore, legally speaking, a situation in which a mutually recognised product is authorised to be placed on the market in different pack sizes in different concerned Member States cannot arise any more because the SPCs of products which have undergone the MRP are and will have to remain harmonised. As a consequence, all authorised pack sizes must appear in the SPC of the RMS and all concerned Member States.

4. "Duplicate applications" in the MRP:

Following a request from Portugal and recent discussion in the MRFG, it was discussed whether and under which circumstances it would be permissible to lodge "duplicate applications" for products which have undergone the MRP. The Commission representative stressed that according to the position taken by the Commission Services, pharmaceutical companies would be allowed to ask for second and third marketing authorisations ("national duplicates") of nationally authorised medicinal products in any Member State (the CMS or the RMS), if the applicant company is INDEPENDENT from the marketing authorisation holder of the first authorisation. Only if the companies are the SAME (=belonging to the same mother company or group of companies or exercising concerted practices) this is not possible and an application for a "duplicate" would have to be submitted to the RMS, followed by mutual recognition of this second authorisation in other CMSs. In this context the Commission representative stressed that the fact that one company sells the right to use parts of its dossier to another company (= allows an "informed consent" application) does <u>not</u> necessarily imply that these two companies must be considered as the same companies.

Certain Members of the Committee pointed out that it might be helpful to reconsider this issue in the MRFG in order to further clarify the Guidance given.

b) Centralised procedure

1. Status Report:

The Commission representative presented an overview concerning the successful operation of the centralised authorisation system and the access of centrally authorised products to the market. He stressed that the sometimes very significant delays concerning the actual placing of centrally authorised products on Member State markets were an issue which deserved further attention. It was announced that a Workshop with industry and Member State participation would look into that issue later this year.

2. Guideline on the packaging information of medicinal products authorised by the Community;

The Commission representative presented a proposed revision 2 of the "Guideline on the Packaging Information of Medicinal Products for Human Use Authorised by the Community", amending paragraph 5 of Section C (concerning the possibility to mention a "local representative" in the blue box) and Annex 1 (PHARM 251) and the Committee approved this revision.

3. Sampling and testing of centrally authorised products

The Council of Europe representative presented a report (PHARM 254) on the satisfactory results of the trial phase of the sampling and testing of centrally authorised products according to the procedure laid down in PHARM 178 (submitted to the Pharmaceutical Committee in September 1997). The Committee took note of this report

and agreed that – after the end of the trial phase - this procedure would now be regarded as fully operational.

c) Notice to Applicants
The Commission representative updated the Committee on the work going on in the NTA Group: The next meeting is scheduled for 28.-29.4.1999 and the main points on the agenda will be the revision of Volume 2, chapter 2 (MRP), chapter 4 (centralised procedure); variations; part I A; renewals; and applications for variations vs new applications.

4. RATIONAL USE OF MEDICINAL PRODUCTS

1. Results of DK-questionnaire on names
The Danish representative presented the results of a questionnaire on names of medicinal products, performed by DK within the context of the EMACOLEX group (PHARM 244) and summed up that regulations and administrative practice in Member States were quite divergent. The Commission representative thanked DK for the precious work and suggested that the results of the questionnaire might serve as a basis for further studies and possible regulatory activities in this field.
In the context of the discussion arising from this paper, some Members of the Committee addressed the issue of "umbrella names". Representatives of those Member States which currently allow "umbrella names" expressed their regret about the fact that they had allowed "umbrella names" in the past and announced that they would try to limit this practice in the future. Representative of Member States which currently do not allow umbrella names felt confirmed in their position and announced that they would not change their restrictive attitude.

2. Harmonised approach concerning the requirement to change the name of a medicinal product following a "switch" from Rx to OTC status ?
The Commission representative pointed out that a number of Member States required the name/trademark of a medicinal to be changed following a switch from Rx to OTC status. Such national practice would - strictly speaking - not conflict with Community pharmaceutical legislation. According to the Commission representative there were, however, several reasons why a more harmonised approach on this issue should be encouraged/discussed:

1. The name of a medicinal products serves as a key identification factor for the product. Some patients, pharmacists and doctors complain that changes in the name of a medicinal product (following the switch of a product) leads to confusion.
1. Industry complains about the additional costs that are caused by the need to promote the new name/trademark of a switched product.
2. The November 1998 Commission Communication on the Single Market for pharmaceuticals identified restrictions in the use of the same tradename for products switched from prescription to non-prescription status as an obstacle for the development of the single pharmaceutical market

It was suggested that one way forward would be to agree on an addendum to the "Switching Guideline" which would deal with the particular issue of the name of switched products. Concerns about possible negative effects of a more liberal approach, namely

1. conflicts with the advertising Directive 92/28 (indirect effect of advertising for the OTC product on Rx-products with the same trademark)
2. effects on the sale of (reimbursed) Rx products with the same trademark

could be appropriately addressed and sorted out within this context.
The Commission representative presented a draft addendum to the switching-Guideline (PHARM 246) for discussion. Whilst numerous Members of the Committee agreed with the aims and purposes of this proposal, representatives of three Member States declared that they could not accept the proposed approach (mainly for the possible negative effects outlined above). Following the clear statements of the representatives of these member States, the Commission representative announced that the Commission was of course not intending to enforce a solution which was not acceptable by everybody. He expressed, hope that the issue might be solved and a harmonised solution be accepted in the future.

5. GOOD MANUFACTURING PRACTICE

The Commission representative presented the following documents, which had been drafted and approved by the Inspectors' group:
1. Community basic format for Manufacturers Authorisation
2. GMP Inspection report - Community format (for inspections requested by either the CPMP or CVMP in connection with applications for marketing authorisations and with products authorised under the centralised system)
3. Guideline on the preparation of reports on GMP inspections requested by either the CPMP or CVMP in connection with applications for marketing authorisations and with products authorised under the centralised system to the Committee and the Committee approved them.
(PHARM 242 and PHARM 242add)
It was announced that the documents would be translated and published in Volume IV shortly.

6. INTERNATIONAL RELATIONS

a) ICH

The Commission representative presented to the Committee a Report from the Steering Committee and Expert Working Groups meeting in Brussels 8 -11 March 1998 (press release – PHARM 255). It was noted that the ICH Steering Committee had been preceded by a meeting to discuss better regulatory co-operation between the regions and that some attempts at sharing pharmacovigilance information would begin.

b) Mutual Recognition Agreement

The Commission representative presented to the Committee a progress report on implementation of agreements with USA, Canada, Australia, New Zealand and a progress report on negotiations with Japan and Switzerland (updated table – PHARM 247). He stressed that currently no new MRAs were in the pipeline and that primary attention should be paid to the correct implementation of the existing MRAs. He also stressed that in the case of the MRAs with USA and Canada the transitional period should efficiently be used to prepare the equivalence confirmation.

c) Enlargement

The Commission representative informed the Committee about the preparations for a Pan European Regulatory Forum (PERF) and the terms of reference for the organisation of this initiative (PHARM 256) were circulated. The CADREAC representative informed the Committee about ongoing CADREAC activities, in particular discussions at the recent meeting in Bratislava where the issues of mutual recognition and review of products already on the market had been particularly addressed.

7. INFORMATION SOCIETY IN THE PHARMACEUTICAL SECTOR:
The future structure and operation of working groups in the field of Telematics/pharmaceuticals was the subject of an intensive exchange of thoughts. Following a recent debate within the Group of Heads of Agencies (HoA), the EMEA had produced a "Proposal for Establishment of an EU ICT Forum for Pharmaceutical Regulators". This paper was tabled at the day of the meeting and the EMEA-representative outlined the background and aims of this paper: IT-issues in the pharmaceutical sector play an important role. It was felt by the HoA that the current work of the Telematics Committee was focusing too much on technical issues and that the interaction between this Committee and other Committees as well as political decision makers could be improved. In the EMEA proposal it was suggested to create an ICT Forum which would be composed of high level representatives. This Group would formulate policies and priorities and give guidance to technical sub-committees in the IT field. The Commission representative acknowledged the need for a better decision-making structure, clearer responsibilities and accountability in the IT sector and promised to discuss the EMEA proposal within DG III and other concerned Commission Services and to present a proposal for a way forward, probably before the next HoA meeting.

The representative of the Council of Europe asked for better involvement of the Council of Europe in the future work in the IT field and the Commission representative took note of this request.

8. A.O.B..
The date for the **next meeting of the Committee** had to be shifted and the date is now – provisionally - confirmed for the **27.-28. September 1999**.