Information on the results of the 42nd Pharmaceutical Committee (Brussels, 20 February 1997

IMPLEMENTATION/INTERPRETATION OF LEGISLATION

a) Commission Communication arising from the second "Bangemann-Hearing" on the marketing authorisation systems

The Commission informed the Members of the Pharmaceutical Committee that it was planned to draft a Commission Communication that would address the application and interpretation of Community pharmaceutical legislation with a particular view to the approaching deadline of 1.1.1998 and its effect on marketing authorisation systems. The drafting of this communication would represent a follow-up to the second "Bangemann-Hearing" on the marketing authorisation systems at the EMEA in London in autumn 1996 and it was planned to publish it soon in 1997.

b) Homeopathy

The Committee was informed about a draft 'Commission Report to the EP and Council on the Application of Directives 92/73 and 92/74'. The chairman informed the Committee that the report would be formally approved by the Commission and forwarded to Council and European Parliament this spring. Member State comments would not be necessary at this stage but they would be most welcome and should be expressed in the Council's response to the report. The chairman clarified that the Commission did not intend to present any concrete proposal for amendments to Directives 92/73 and 92/74 before obtaining positive signals from Parliament and Council.

c) Distance selling of medicinal products

The Commission presented background information on existing and planned legislation addressing this issue and stressed that the "Distance Selling Directive" had been finally adopted and was to be published in the Official Journal shortly. Both Member States and the Commission agreed that the main obstacle in tackling the issue was not adequate legislation but difficulties in enforcement. Administrative co-operation between Member States would therefore play an essential role. Different approaches of Member States with regard to distance selling of medicinal products (which would persist even under the new Distance Selling Directive) combined with the abolition of customs control in inter-Community trade would result in making the enforcement of national bans nearly impossible. For this reason some Member States called for a legislative initiative aiming at a Community wide ban on distance selling of medicinal products. The Commission answered that just after the adoption of the Distance Selling Directive such an initiative would have no chance. The Commission also raised the point that under the regime of Directive 92/28 the above problem could only appear with regard to OTC products because advertising to the public (which is a precondition for any form of distance selling) was forbidden for prescription-only products anyway.

LEGISLATIVE PROPOSALS

a) Codification

The Commission informed the Pharmaceutical Committee of a change in its approach vis-à-vis the planned codification/recast of Community pharmaceutical legislation and explained the background to the change of the initial plans: Following the receipt of very divergent wishes and comments from Member States and interested parties in 1996 which would have made it necessary to rethink and redraft most of the existing legislation, it was felt that a two-step approach could better serve the aim of achieving clarity and legal certainty. Phase 1 would consist of a pure technical codification that would merge the texts of existing directives into one text without bringing any changes to the wording of the provisions. Due to the technical character of this exercise, an interinstitutional agreement (providing for simplified procedures) would apply, which would allow step one to be completed in one year. Phase 2 would bring about material changes and adaptations to pharmaceutical legislation deemed necessary in order to obtain a clearer, more comprehensible and up to date text. The work in Phase 2 would be made easier through the results (clear numbering of articles; one consolidated text) already achieved in Phase 1. The Commission confirmed that the work invested in the recast exercise so far was therefore not lost, but could be taken up in Phase 2.

b) Starting materials

The chairman raised the point that there was a strong link between the issue of control of starting materials and the issue of inspection. It would not make sense to propose draft legislation on starting materials before choosing an appropriate approach to the question of a future - Community - inspection system. In this context some Member States emphasised their concern that setting up an inspection system in the Community should respect the principle of subsidiarity and should preferably be based on voluntary administrative co-operation. The Commission stressed that there was growing political pressure from the European Parliament to pay more attention to the issue of inspection in general and to find effective Community solutions in particular. Moreover, MRA negotiations with the US and Canada would have an important impact. Member States were invited to reconsider the issue in the Group of Heads of Agencies. The Commission promised that a basic decision on how to address the question of an inspection system in the Community (through legislation, administrative co-operation or by a "third way") and how to control starting materials would be taken soon and that the Pharmaceutical Committee would be kept informed of future developments.

c) Transmissible Spongiform Encephalitis (TSE)

The Commission's proposal to amend Directive 75/318 in respect of TSE was the subject of a lengthy and intensive discussion.

Some Member States questionned the 'absolute' interdiction of class I and II products provided for in the draft and asked for provision of geographical exceptions for substances coming from TSE-free regions. Moreover they stressed that the 'absolute' interdiction would not be in line with the principle normally applicable for pharmaceutical products : to assess likely risks and benefits. The Commission replied that TSE could not be seen as a geographically limited problem anymore because of the practical impossibility of having 100%-efficient controls and put into question the concept of TSE free zones as such. This fact, combined with insufficient scientific certainty about TSE, required an EU-wide 'security-first' approach. The Commission

also stressed that this measure should be regarded as another step forward and that it did not in any way cast doubt on the efficacy of national measures taken so far in this field. Member States also expressed their concern about the enforceability and control of the proposed provisions. There was general agreement that an exchange of administrative information would be very helpful and necessary for Member States. The Commission stressed that the main target of the proposed provisions - the pharmaceutical industry - had for the most part already implemented production policies that were in line with the draft proposal and that its implementation would therefore not present insoluble problems.
The Commission announced that the draft directive would be submitted to the Committee foreseen in Article 2b of Directive 75/318 in March 1997 and that the measure would be further discussed and possibly adopted in accordance with Article 2c of that Directive. Following specific comments from Member States, the Commission promised to redraft the proposal before submission, in order to allow for the continued use of 'medicinal products for which there is no therapeutic alternative' for a period equivalent to the applicability of the draft directive. Likewise it was decided to redraft some of the recitals in order to explain better the background of the measures taken and thus avoid public concern.
Following comments of Member States the Commission also confirmed that it would notify the measure under the relevant international agreements and explain the measure to the EU's main trade partners.

d) 'Good Clinical Practice in the conduct of clinical trials' and 'Orphan medicinal products'
The Commission reported on a very productive meeting with Member States in which the draft GCP-Directive was further considered and a number of draft guidelines identified. The draft GCP-Directive would also be subject of an intergroup discussion with the European Parliament in March 1997.
As regards the draft Regulation on Orphan medicinal products, the Committee was informed that a fifth revision was being prepared, taking account of some very useful comments of experienced US-colleagues. It was announced that the draft Regulation would perhaps be taken up as a package together with an orphan drug programme of DG V later in 1997.

RATIONAL USE OF DRUGS

a) Update on draft guidelines on the excipients in the label and package and on the readability of the label and package leaflet of medicinal products for human use
The Commission informed the Committee that comments on these draft guidelines were still arriving and that revised versions would be discussed in the Ad-hoc Group on Labelling. Final drafts would then be presented to the next Pharmaceutical Committee on 11.6.1997.

b) Commission Report on the application of Directive 92/26
The chairman announced that some more comments from Member States still had to be included and that the Commission would subsequently adopt the report.

MARKETING AUTHORISATION PROCEDURES

a) Centralised procedure

1. Status Report.

The Commission stated that no significant changes had taken place since the last Pharmaceutical Committee. A subsequent discussion between Member States and the Commission showed that there was concern with regard to the question of different pack sizes and the centralised procedure. The Commission concluded that harmonisation of pack sizes in the EU would be desirable in the long run and that a mandate to CEN should be envisaged. It was decided to take up this issue in possible future expert meetings.

2. Parallel Distribution of Centrally Authorised Medicinal Products Commission Working paper

The Commission informed the Committee on its draft note concerning the parallel distribution of centrally authorised medicinal products. It was made clear that the paper represented an internal note which would express the Commission's view of the issue (taking into particular account recent judgements of the European Court of Justice) and that the note itself had no binding legal effect.

Member States expressed their strong interest in the subject and asked the Commission for clarification on certain points. The questions raised concerned particularly

- the admissibility of national fees for checking the parallel distributed product;
- distribution of competences between national and Community authorities;
- practicability of tight time-limits and
- identification of the parallel distributor on the packaging of the repackaged product.

The Commission agreed to clarify these points when redrafting the text.

3. Single Trademark

Owing to pressure of time and as no real problems had arisen so far, this item was postponed. The Pharmaceutical Committee would be informed of any new developments.

4. Update on draft guideline on the packaging information of medicinal products for human use authorized by the Community

It was announced that the draft Guideline was currently being updated, taking account of Member States comments received and the results of discussions in the Legal Status Working Group of 14 February 1997.

In this context the Commission affirmed that - in particular with regard to Article 12 of Regulation 2309/93 and Article 5 EC - Member States must find suitable ways to allow the marketing authorisation holder (MAH) of a centrally authorised product to fulfil all conditions laid down in the Commission Decision granting the marketing authorization. This would imply that national authorities had to provide for an administrative, legal or practical framework that would allow the MAH of a centrally authorised product to have his product put on the market under the specific condition of legal status laid down in the decision. This need not necessarily be done by introducing optional subcategories of legal status into national law, but might also be achieved by other practical measures.

The Commission also alerted Member States that a change to this legal situation could only be achieved through an amendment of Regulation 2309/93, requiring - inter alia - unanimity of Member States.

5. Guideline on centrally authorised vaccines

The Pharmaceutical Committee was reminded of the text of this Guideline, upon which comments had been invited before 31.3.97.

b) Mutual recognition

1. Oral Status Report (NL)

The Dutch delegate reported on relevant activities (Meetings of Heads of Agencies, meeting of officials concerned) which would serve the purpose of increasing mutual understanding and exchange of information. He also alerted the Commission to the fact that there was a need for clear and unambiguous interpretation of Community law with regard to the mutual recognition procedure (in particular concerning the handling of generic applications). He also mentioned problems concerning the phasing-in of certain telematic applications.

The Commission thanked the Dutch presidency for its presentation and expressed its firm commitment to continue to pay particular attention to the mutual recognition procedure and its application. According to the Commission, an important step forward (including legal clarifications) could be expected from the planned Commission. Regarding the phasing-in of telematic applications, the chairman stressed that the Commission was co-operating intensively with Member States to make EUDRANET and EUDRATRACK fully operational soon and that significant resources had been invested in these important projects.

2. Herbal remedies, nomination of experts, Copy of a letter addressed to Member States;

The Commission reminded Member States of the letter sent out in January 1997, asking for the nomination of experts in the field of herbal remedies. As already pointed out at the last (41st) Pharmaceutical Committee, it was clarified that this “group of experts on herbal remedies” would be primarily established within the EMEA. It would pool the experiences of Member States in herbal remedies and it would liaise with CPMP on all questions concerning herbal remedies. Simultaneously this group would advise the Commission on the ongoing study on herbal medicinal products and on possible legislative measures to be envisaged.

The Commission added that one of the first issues to be addressed by the group would be the development of particular guidance concerning the proof of safety and efficacy of herbal remedies (in particular by references to scientific literature). It was suggested that this issue could also subsequently be taken up in the “Notice to Applicants”.

3. Non clinical testing requirements of well known compounds

Member States and the Commission agreed that the “report of non clinical testing requirements” was a valuable document which contained some interesting approaches and which provoked fruitful discussions. It was, however, also agreed that on both legal and practical grounds it should not be adopted as a Guideline. The Commission announced that as appropriate, the issue would be addressed in the planned Commission Communication.

4. Flu-vaccines; practical solutions to address the issue in the mutual recognition procedures

Member States strongly welcomed the proposal presented by the Commission to address the issue of flu-vaccines in the mutual recognition procedure. In essence it was proposed and agreed to apply a two step approach consisting of

1. a core registration for each flu-vaccine (to be mutually recognised) and
2. annual updates to be mutually recognised through a “fast track”.

The Commission agreed to propose an amendment to the Variations Regulation which would be necessary in order to facilitate the "fast track" and stressed that the year 1997 could be already used for a 'warming-up' exercise.

5.Mutual recognition of generic products

The Commission assured Member States that it was actively looking for a pragmatic solution which would not conflict with legislation and which would ensure that public health would not be at risk. The Commission announced its intention to present a solution soon and to take up the issue in the planned Commission Communication (see item 3.a). Member States were asked to actively support the Commission and to be ready to accept more flexible approaches. The Commission announced that a meeting would take place on 18 April to discuss the consequences/effects of the end of the transition period (1.1.1998)

6. CFC's in metered dose inhalers and the Montreal Protocol

Unfortunately there was insufficient time to discuss this additional item in detail and the Commission promised to send out a letter to the Members of the Pharmaceutical Committee.

c) Article 11&12 of Directive 75/319, Status Report

Unfortunately there was insufficient time left to cover this item.

d) Notice to Applicants

1. Report of meeting on 26.-27. November 1996 and 6.-7. February 1997.

The report of the meeting on 26.-27. November 1996 was tabled and it was announced that the report of the meeting on 6.-7. February 1997 would be distributed for the next Pharmaceutical Committee.

2. Vol. II B, (tabled for information)

Copies of the January 1997 publication of Volume II B were circulated to all Members of the Committee.

e) rDNA - manufacturing changes

There was insufficient time left to fully cover this item. The attention of the Members of the Committee was, however, drawn to the EFPIA position paper on the issue and the Commission asked for further written comments. It was also announced that the issue could possibly be resolved through an amendment to the Variations Regulation.

INTERNATIONAL RELATIONS

a) ICH

Following questions from Member States, the Commission confirmed that the future of ICH would be addressed at the upcoming Steering Committee in Narita and that one of the key issues for the future would be the development of a 'common technical document'. The Commission alerted Member States to the fact that work on this project would be based on their support and that this also had serious resource impacts. Member States - being aware of these circumstances - noted the development and their role in the process.

Unfortunately there was insufficient time left to fully cover all items. (The issues were however discussed the following day in a special meeting on ICH.)

b) Relations with 3rd countries

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

The Chairman informed the Committee that intensive discussions were currently under way with the USA and that no significant changes had taken place with regard to the other countries since the last (41st) meeting of the Pharmaceutical Committee.

2. Bilateral meeting European Commission(DG III) and US-Food and Drug Administration FDA

There was insufficient time left to cover this item.

c) European Economic Area (EEA)

The Commission informed the Committee that EEA countries will soon be subject to the full scope of Community Pharmaceutical legislation including Regulation 2309/93, after a basic agreement on financial aspects had been reached. However some administrative steps would still be necessary before the relevant legal texts could enter into force and it was promised to keep the Pharmaceutical Committee informed on the issue.

d) Central and Eastern European Countries (CEEC) - Unilateral recognition of Community marketing authorizations

Arising from the comments received, all Member States welcomed the proposal and the invitation to work more closely with the CEEC. It had emerged from the contributions received that a two step approach could be envisaged namely to commence with Community marketing authorisations and thereafter expand to include marketing authorisations following mutual recognition. This would allow for the development of procedures for on-going liaison, esp. variations and pharmacovigilance which could apply in the 2nd phase. A rework of the draft Notice to Applicants would be prepared. The Commission announced that the unilateral recognition of Community marketing authorizations would be considered in a meeting with CEEC countries.

A.O.B.

Counterfeit medicinal products

Member States were informed on a media report concerning the issue.

Gene therapy (compilation of studies),

The text of the study was tabled for information and the Commission announced that a letter would be sent out, concerning future action in this field

Next meeting of the Pharmaceutical Committee:

The next meeting was scheduled for the 11. June 1997.