***INTRODUCTION***

At the 12th meeting of EMACOLEX[1] in Helsinki 11 & 12 November 1999 the main point under discussion was the interpretation of Article 4.8(a) of Directive 65/65/EEC. Considerable efforts were made in order to achieve agreement between legal officers representing 13 out of 15 medicines agencies of Member, the EMEA and the European Commission about the interpretation of the article following the Judgement of the European Court of Justice (ECJ) in the "Generics case" C-368/96.

***THE PREPARATORY MEETING***

Earlier, at a meeting on 25 August 1999 in Bruxelles, a task force of EMACOLEX comprised of representatives from the medicines agencies of Denmark, Finland, Ireland, the Netherlands, Sweden, the United Kingdom, the Commission and the EMEA had tried to achieve a consensus on a viable interpretation of all elements of the abovementioned article.

***THE WORKING DOCUMENTS OF THE HELSINKI MEETING***

In order to facilitate the discussions three participants had prepared working documents. The EMACOLEX adopted the three documents as the basis for discussions in the plenary as well as in the four working groups that EMACOLEX had decided to set up for the meeting.

***THE FIRST PLENARY***

All three documents were very briefly introduced, after which a round-table discussion in the plenary took place. From this discussion two starting points for discussion, or basic principles of interpretation emerged:

- that a balance - within the wording of the provision at issue as interpreted by the ECJ - had to be maintained between the interests of the marketing of generic medicinal products on the one hand and the development of innovative medicinal products on the other hand.

- that the data protection provision was originally intended to avoid repetition of animal tests and clinical trials.

***THE WORKING GROUPS***

After the round table discussion, the plenary was divided into 4 working groups to discuss the issues. The result of the discussions in the working groups were presented afterwards by the appointed rapporteurs of the group(s). Some points lead to a near or complete agreement, but other - more fundamental - issues remained open for further discussion.

[1] European Medicines Agencies co-operation on Legal and Legislative issues. The group is informal and it started its work year 1994 at the first meeting of legal officers (the name **EMACOLEX** were adopted at this meeting)

**POINTS OF AGREEMENT:**

**1)** A large majority agreed that an abridged application must refer to a dossier at the disposal of the competent authority and connected to an authorised product.

**2)** A generic marketing authorisation may be granted, if the dossier for the reference product is "alive" at the time of application, even if the marketing auhorisation for the reference product has been withdrawn for commercial reasons before the granting of the generic marketing authorisation.

**3)** There seemed to emerge general agreement concerning the fact that an abridged application can only refer to an existing marketing authorisation. This means that the abridged procedures cannot be used for simultaneously submitted "double applications." On the other hand participants were not sure if it would not be better to find creative solutions, if no public health concerns exist regarding doubling the dossiers.

**4)** The concepts of essential similarity and the 6/10 year protection period were discussed on the basis of the provision at issue, Art. 4.8.a (i) and (iii), and the judgement in the Generics case. Before initiating the discussions the terminology in the field was explored in order to be able to discuss the matter properly. It became evident that participants understood the term "medicinal product" as including all existing pharmaceutical forms, strengths and indications of a given substance with a trade name. Furthermore it was agreed that a specific pharmaceutical form and strength of a product should be called a specific "presentation" of the product in question.

A large majority agreed that i*n the context of this special provision* the term "same pharmaceutical form" must be understood broadly, meaning that essential similarity can be established between different oral pharmaceutical forms (e.g. tablets and capsules) for immediate release and that subsequent pharmaceutical forms and strengths for an original product is not protected by a new 6/10 year period.

In EMACOLEX the earlier understanding of the Pharmaceutical Committee was therefore confirmed.

*Bioequivalence* should be substantiated, if appropriate.

The legal basis for this interpretation is the Generics case when read in connection with Article 4.8.a (iii). If a generic product is not essentially similar with the reference product in the sense that is agreed upon and mentioned above, it may still be authorised cf. the second sentence of (iii), if appropriate supplementary documentation is submitted.

"Appropriate supplementary documentation" is basically a concept of scientific nature, and is therefore, as such, subject to interpretation by competent authority

of what is necessary to protect public health vis á vis the documentation already in the possession of the competent authority.

**5)** EMACOLEX agreed that the term "*is marketed"* in article 4.8(a) should be interpreted in a pragmatic way as "*has a valid marketing authorisation*".

**6)** Everybody agreed that an abridged marketing authorisation is not affected by the withdrawal of informed consent, at least until the expiry of the 5 year period. What happens in the renewal procedure is not agreed upon.

***THE SECOND PLENARY***

The plenary meeting agreed, from a purely legal point of view, that the provision under discussion is very unclear and is in dire need of being redrafted in a more clear and precise manner.

During the discussion a suggestion was put forward as to whether - after the expiry of the 6/10 year period – parts III and IV of the documentation presented in an application could be *passed on* to any applicant under the abridged procedure. It could be argued that commercial interests associated with parts III and IV were no longer worthy of protection after the expiry of this period. This question needed further thought at the various national levels. The answers would to a large extent depend on the contents of national legislation on public access to administration files.

However, at community level it would also be relevant to ascertain whether or not pharmaceutical law contained any legally binding requirements for holders of marketing authorisations, based upon abridged applications, to update parts III and IV of the application. If this were the case, such marketing authorisation holders would be placed in an impossible situation. How could they comply, if they did not have access to parts III and IV ? On the face of it, there seemed to be little or no difference between

1. accepting subsequent applicants to refer "blindly" to parts III and IV of the first application and
2. parts III and IV being in the public domain and passed on upon request.

Furthermore, participants agreed that- if an answer to the question described above could not be found in the existing wording of the provision - it should be considered, as a principle of any future legislation, that the discussion concerning these data should be deemed to have an ethical dimension. Since animal tests and clinical trials imply sacrifices from both animals and humans, it could well be argued that data deriving from such investigations should not be at the sole disposal of the sponsor, to be discarded if he so wishes. This is also important due to the fact that GLP and GCP provisions prohibit repetition of these tests and trials. Therefore, in future legislation it could be stipulated that after the expiry of the data protection period these data should be in the public domain for use by any generic applicant. Such an approach would resolve the contentious issue of whether or not there exists a link between the first and subsequent applications.