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Brussels, October 1983

THE EUROPEAN COMMON MARKET IN MEDICINES TAKES A NEW STEP FORWARD

1. The European common market in medicines has taken a significant step forward with the adoption by the "Internal Market" Council of 26 October 1983 of a new Directive and a Recommandation concerning medicinal products for human consumption.
   Much remains to be done, however, before it is fully in operation. The European Parliament, in its Resolution (1) on the production and use of pharmaceutical products, recently pointed out the many tasks to be accomplished in this sector.

2. As the Commission sees it, real progress has been achieved, although it is still too slow and laborious, in the harmonization of the laws governing the marketing of medicines. Thank to the new Directive and the Recommandation, Community legislation, which already includes several directives, is strengthened and enlarged in some important aspects :

   - the competent authorities will summarize the characteristics of each medicinal product when it is granted marketing authorization.
   - the interest of the patient, the working on the label will be entended to include the International Non-proprietary Name and the last date of use;
   - the standards governing the quality of manufacture are improved;
   - mutagenisis and bio-availability are laid down as two new types of test.

3. In addition, the Recommandation, which is the result of five years of work by government experts, gives a common and detailed interpretation of five important aspects of Directive 75/318/EEC , namely : tests for acute toxicity, carcinogenicity, reproduction and pharmaconetics on animal subjects and the criteria to be applied to medicines comprising more than one active principle.

4. The new Directive strengthens the coordination of the marketing authorizations granted by the Member States by improving to an appreciable extent the present procedure used by the Committee for Proprietary Medicinal Products:

   - this procedure is made much easier for the pharmaceutical companies in that, in future, they will be able present their case to the Committee orally or in writing and submit their applications to two Member States instead of to not less than five Member States as required previously;
   - for their part, the authorities must duly take account of an authorization already granted by the first Member State and, to this end, they will be able to refer to all the orginal documentation and to the official summary of the characteristics of the product. If it is a new medicine, they will be given access to the critical evaluation of the dossier compiled by the first examining Member State ;
   - finally, the Commission will now play a more active part in this Committee by being able to seek its advice on whether certain decisions taken by the Member States reflect the provisions of the Treaty and the criteria laid down in the pharmaceutical directives.

(1) Resolution of 14 April 1983, OJ N° C 128, 16.5.1983
(2) Directive 65/65/EEC of 26 January 1965, OJ N° 22, 9.2.1965
Directive 75/318/EEC of 20 May 1975, OJ N° L 147, 9.6.1975
Directive 75/319/EEC of 20 May 1975, OJ N° L 147, 9.6.1975
Directive 78/25/EEC of 12 December 1977, OJ N° L 11, 14.1.1978

5. In spite of the progress achieved today, the objective of a common market in medicines, a desirable objective from the point of view of both the patients and the pharmaceutical industry, has not yet in fact been achieved. Consequently, the Commission will, by calling for increased efforts by the competent authorities of the Member States and the pharmaceutical companies, try to secure the recognition of the marketing authorizations granted for medicines, which it feels, for its part, is the best means of ensuring the free movement of medicines in the Community. As and when necessary, the Commission will put forward proposals aimed at attaining this objective.