

The National Procedure

Until 1998, the pharmaceutical industry could apply for a national approval. The product can then only be sold in that particular EU country. A marketing authorisation (MA) is valid for five years and after the first renewal, the MA is valid for an unlimited period. In order to obtain an approval the product must be submitted with an SPC (Summary of Products Characteristics) which is the basis for the marketing of the product. For some products, i.e. products intended for national use in one Member State only, it will be possible to use the national procedure also after 1998.

The Mutual Recognition Procedure

Mutual recognition means that EU countries may approve the decision made about a medicinal product by another EU country. The pharmaceutical company submits their application to the country chosen to carry out the assessment work, which then approves or rejects the application. The other countries have to decide within 90 days whether they approve or reject the decision made by the original country. Two groups are working for the facilitation of the Mutual Recognition Procedure : for human medicinal products, the CMD(h) (Coordination Group for mutual recognition and Decentralised procedures (human)), and for veterinary medicinal products, the CMD(v) (Coordination Group for mutual recognition and Decentralised procedures (veterinary)). If a member state cannot approve the assessment report, the summary of product characteristics, the labelling and the package leaflet on grounds of potential serious risk to human and animal health or to the environment, a pre-referral procedure should be issued by the relevant Co-ordination Group. If the Member State(s) fail to reach an agreement during the 60-day procedure of the pre-referral, a referral to the CHMP/CVMP for arbitration may be made through its secretariat at the EMEA.

The Decentralised Procedure

The decentralised procedure should be used for products that have not yet received authorisation in an EU country. The applicant may request one or more concerned Member State(s) to approve a draft assessment report, summary of product characteristics, labelling and package leaflet as proposed by the chosen reference Member State in 210 days. The two groups, CMD(h) and CMD(v), also work for the facilitation of the decentralised procedures. If a member state cannot approve the assessment report, the summary of product characteristics, the labelling and the package leaflet on grounds of potential serious risk to human and animal health or to the environment, a pre-referral procedure should be issued by the relevant Co-ordination Group. If the Member State(s) fail to reach an agreement during the 60-day procedure of the pre-referral, a referral to the CHMP/CVMP for arbitration may be made through its secretariat at the EMEA.

The Centralised Procedure

An approval for a medicinal product intended for use in all EU countries may be obtained by applying to the EMEA (European Medicines Agency) in London. Within the EMEA two scientific committees have been established : for human medicinal products, the CHMP (Committee for Medicinal Products for Human Use) and for veterinary medicinal products, the CVMP (Committee for Veterinary Medicinal Products). These committees prepare an opinion preceding the formal approval by the Commission. The member states have one representative in each committee. The assessment work of the application is done by any of the EU countries. When EMEA has received a centralised application the responsible committee appoints a rapporteur/co-rapporteur. On the basis of the opinion from the scientific committees the Commission (or the Council) issues the formal decision to authorise a product in the centralised procedure. The Commission is assisted in the decision-making procedure by a Standing Committee with representatives from each Member State.