Authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

2001/0252(COD) - 10/12/2002 - Modified legislative proposal

The Commission has accepted 45 amendments proposed by the European Parliament at first reading, including: - a negative risk/benefit analysis is included as a reason for withdrawing a medicinal product from the market; - two amendments aimed at strengthening the inspection of the manufacturing sites of the applicant for medicinal products for human and veterinary use; - four amendments aimed at shortening the time limit for the decision-making process; - the requirement to publish information concerning the refusals or negative opinions for applications for marketing authorisation; - the provisions aimed at altering the period of validity of the marketing authorisation in the case where this has not been followed by the placing on the market of the medicinal product. The same provision is introduced in the case of previously authorised medicinal products which have not been on the market for a certain period; - the introduction of a derogation from the rule that a marketing authorisation is valid for three years; - an amendment aimed at preventing the marketing authorisation holder from providing pharmacovigilance information without the consent of the Agency; - certain amendments aimed at modifying the method of nominating and of working of the Committees of the Agency - the functions of the Agency are modified, concerning inspections of compliance with good practices; - the contents of the database on medicinal products must be specified; - documents prepared must be published in the event of disagreements between the Agency and a scientific committee; - the contents of the code of conduct of the Agency must be specified, and the declarations of interest of the Members of the boards and the committees of the Agency must be published and made accessible on request; - the executive director shall cover the activities of the Committee on Herbal Medicinal Products in the context of his responsibilities; - two amendments aimed at modifying the composition of the Management Board; - provisions aimed at reviewing the finances of the Agency; - the possibility of helping small and medium-sized pharmaceutical firms at the time of submission of marketing authorisation applications or applications relating to diseases with a regional distribution is extended; - at the request of the Agency, the names of marketing authorisation holders subject to financial penalties from the Commission must be made public. The Commission accepted some 58 amendments in part or in principle. These include: - two amendments aimed at providing particular support to SMEs by reason of the extension of the scope of the centralised procedure to all medicinal products containing a new active substance. These measures are aimed at reducing the costs associated with the request for authorisation submitted to the Agency and to facilitate the requests for scientific advice. Rewording is necessary to indicate the possibility of a specificbut not dispensatory system for these companies and to indicate specifically, but not exclusively, the ability of SMEs to request scientific advice; - the introduction of an arrangement to provide for a reduction in fees payable by SMEs; - the reference to the principle of comparative efficacy. It is emphasised that the evaluation is not considered a necessary criterion for the application or authorisation of medicinal products; - the application of the ethical requirements of Directive 2001/20/EC on the implementation of good clinical practice in the conduct of clinical trials on medicinal products authorised by the Community as well as the application of the same requirements to clinical trials conducted outside the Community on medicinal products destined to be authorised by the Community; - the provision concerning Directive 89 /105/EC and the conduct of a specific study on its implementation; - the principle concerning the naming of generic medicinal products of reference products authorised through the centralised procedure. The international non-proprietary name and its translation into the different languages of the Member States are considered as equivalent in all Member States; - the principle aimed at including an accelerated procedure for medicinal products used in certain treatments with a view to making them available to patients more quickly; - specific provisions for the publication of the opinions of the committee of the Agency concerning conditional authorisations, assessment reports, summaries of product characteristics,

labels and package leaflets as well as information related to suspected adverse effects of medicinal products and urgent decisions aimed at suspending the use of a product, by reference to the implementation of Regulation 1049/2001; - the provision of public funding commensurate with the pharmacovigilance activities carried out by the Agency; - the role of patients in the communication of adverse effects; - the specification of the contents of the guidance developed for the verification and presentation of adverse reaction reports; - strengthened coordination between the national pharmacovigilance systems and the Agency. The Commission does not accept 50 amendments. These include: - an obligation for the Commission to prepare a specific regulation establishing a policy for orphan medicinal products for veterinary use - the provision that all new medicinal products authorised by the Agency must include the phrase "newly authorised medicinal product" as well as an invitation to patients to report any adverse effects and an obligation for the marketing authorisation holder to handle any information reported directly by the patient.