Medicinal products for human use: Community code

2001/0253(COD) - 02/10/2002

The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, F) tabling a large number of amendments to the proposal under the codecision procedure (1st reading). The main amendments were as follows: - the committee deleted the proposed derogation to the basic rules which would allow the pharmaceutical industry to provide information on medicines for AIDS, asthma and diabetes, on the grounds that this would be the first step toward consumer advertising of prescription medicines in the guise of 'disease education'. The industry was incapable of providing impartial information on its medicines and such information should therefore only come from independent sources; - it was proposed that the Commission should develop an information and education strategy to ensure that all patients could obtain objective, reliable and non-promotional information about medicines and other treatments; - the committee adopted a large number of amendments aimed at ensuring greater transparency and access to information for the public (including publicly-accessible registers and databases on medicinal products), as well as provisions on the legibility and clarity of packaging and patient information leaflets; - to speed up the time within which generic medicines can be brought onto the market, applicants should not be required to provide the results of pre-clinical tests or pre-clinical trials if they can demonstrate that the medicinal product is a generic of a reference medicinal product authorised for eight years in a Member State or in the Community, rather than ten years as proposed by the Commission. The committee added, however, that such a generic medicinal product cannot be manufactured or placed on the market until ten years have elapsed since the first authorisation of the reference product and that, in the case of a biogeneric medical product, pre-clinical tests and/or clinical trials shall be necessary; - generic drugs should be identified in all Member States with the same denomination of the internationally approved chemical name of the active substances and the name of the producer; - authorisation applications should include a confirmation that clinical trials for the medicinal product in question have not been carried out in developing countries unless that product is primarily geared to the domestic market in those countries; - in the first five years after being placed on the market, the package leaflet must bear the phrase 'Newly authorised medicinal product. Please notify any adverse reactions'; - Member States should be able to temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of a pathogen which could cause harm.