Medicinal products for human use: Community code

2001/0253(COD) - 27/11/2003

The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, F) amending the Council's common position under the 2nd reading of the codecision procedure. It retabled a number of key amendments adopted by Parliament at 1st reading which had not been accepted by Council: - the procedure for granting a marketing authorisation for medicinal products should be completed within 150 days (rather than 210 days as proposed) after a valid application has been submitted, including 80 days for scientific data analysis and preparation of the assessment report; - for the purposes of authorising medicinal products for human use, clinical trials carried out in a developing country should not be recognised, unless the product concerned primarily benefits the population of that country; - as regards data protection for pharmaceutical companies, it should be possible to extend the ten-year protection period up to a maximum of eleven years if, during the first eight of those ten years, the marketing authorisation holder obtains an authorisation for new therapeutic indications bringing "significant clinical benefit" in comparison with existing therapies; - a new article should be inserted on the procedure for the granting of compulsory licences, in the light of the WTO decision of 30 August 2003 on implementing paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health; - after consulting patients', doctors', consumers' and pharmacists' organisations, Member States and other interested parties, the Commission should present a report on current practice with regard to information provision - particularly on the Internet - and its risks and benefits for patients. If appropriate, the Commission should put forward proposals setting out an information strategy to ensure good quality, objective, reliable and non-promotional information on medicinal products and other treatments. The question of the information source's liability should also be addressed; - national authorities should set up a publicly accessible database, independent of pharmaceutical companies, containing updated package leaflets for all pharmaceutical products licensed for sale or dispensing. The database should be structured in such a way as to make a comparison possible of the information available for all medicinal products; - Member States should set up appropriate collection systems for unused or time-expired medicinal products via pharmacies; - activities connected with pharmacovigilance, the functioning of communication networks and market surveillance should receive public funding.