Medicinal products for human use: Community code

2001/0253(COD) - 29/09/2003 - Council position

The Council's common position incorporates 20 amendments adopted by the European Parliament, which had been taken up unchanged in the Commission's amended proposal. In addition, the Council has accepted in part or in principle 42 amendments adopted by the European Parliament, which have been endorsed at least partially or in principle in the Commission's amended proposal. The Council has agreed on a number of changes, including editorial ones, to clarify the provisions of the text, to update terminology or to align the text with the proposal for a Regulation and the proposal for a Directive on medicinal products for veterinary use. The more substantial changes are described below: - deletion of the possibility to extend the data protection period to 11 years when a new therapeutic use is found for a new product; - deletion of the proposal to harmonise of the legal status of a medicinal product; - the Council has changed the provision on the choice of Committee procedure in relation to decisions to be taken by the Commission following an opinion from the scientific committee. The Council does not consider it consistent with Decision 1999/468/EC to have two different procedures for decisions having the same object and believes that the management procedure is the appropriate procedure to apply for these decisions; - the Council has provided for the possibility of adoption of amendments to the arrangements concerning the periodic safety update reports through a Committee procedure in the light of experience gained; - to improve availability of medicines - particularly in smaller markets - a new article 126a has been introduced that will allow a Member State for public health reasons and under certain circumstances to grant an authorisation for a medicinal product authorised in another Member State; - Article 32 (5) of the Directive allows for the scientific committee to give recommendations for conditions and restrictions in respect of nationally authorised products. The new Article 127a provides for adoption through comitology of decisions requiring Member States to implement such conditions and restrictions in relation to the safe and effective use of centrally authorised products, including vis-à-vis third parties. Other changes include: - adjusting some time limits in relation to the evaluation procedure; - strengthening the supervision powers of the competent authorities by providing them with the explicit right to request the submission of data from the marketing authorisation holder at any time (Article 23); - a new Article 23a has been inserted that requires the marketing authorisation holder to inform the competent authorities of the date of marketing of the medicinal product and any withdrawal from the market of the product; - extending the requirements on good manufacturing practice to certain excipients; - extending the duty of the marketing authorisation holder to report adverse reactions occurring in the territory of a third country; - extending the scope of the provision in Article 111 on inspections.