Medicinal products for human use: Community code

2001/0253(COD) - 26/11/2001 - Legislative proposal

PURPOSE : to amend Directive 2001/83/EC on the community code relating to medicinal products for human use. CONTENT : In general terms the pharmaceutical legislation needs to be revised (see COD010252), in view of lessons learnt as well as scientific and technical progress. The main amendments are as follows: -the definition of medicinal product is adapted to take account of new therapies and their particular mode of administration. -since the possible duality of certain "borderline" products (medical devices, cosmetics, biocides etc.) has led to differences of opinion as to the applicable legislation, it is proposed that when a product fully meets the definition of a medicinal product, but may also meet the definition of other regulated products, the pharmaceutical legislation should apply. -adaptations are proposed to certain provisions relating to the marketing authorisation application file. -in the case of abridged marketing authorisation procedures, the concept of "essentially similar" medicinal products is abandoned since it actually refers to generic medicinal products, a definition of which is inserted, together with a definition of reference medicinal product. -the administrative protection period for data on the reference medicinal product is harmonised at ten years. -any medicinal product not compulsorily subject to the centralised procedure will be covered by the decentralised or mutual recognition procedure, on condition that it is intended for the market of more than one Member State. These procedures are thus still optional for other medicinal products which represent a therapeutic innovation and will be the procedure of choice for generic medicinal products. -the mutual recognition procedure has been criticised because of difficulties encountered in practice. Added to the general principles of mutual recognition is a new decentralised procedure for medicinal products not yet authorised in the Community, where Member States would cooperate before a decision is taken by one of them. -the establishment of the co-ordination group to whom disagreements are referred under the new decentralised procedures. -the obligation to renew marketing authorisation every five years is removed. (see COD010252) -the referral procedure is amended, and the overall length is reduced from 90 days to 60 days. -Commission decision-making is to be subject to a consultation procedure and a management procedure, depending on the case. -on inspection and surveillance matters, it is proposed that the regulation be extended to cover active substances used as starting materials in the manufacture of medicinal products. Provision is made for issuing certificates of good manufacturing practice attesting compliance with the relevant requirements. -there are provisions to ensure a greater emphasis on a preventive approach with regard to pharmacovigilance. -the proposal introduces a limited mutual recognition procedure for homeopathy. Invented names may be used. The blanket prohibition on advertising is removed.