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

2001/0252(COD) - 26/11/2001 - Legislative proposal

PURPOSE : regulation to establish the new procedures for the authorisation and supervision of medicinal products and to establish a European Agency for the Evaluation of Medicinal Products ("the Agency"). CONTENT : This regulation repeals Regulation 2309/93/EC. There are four main objectives: -to guarantee a high level of health protection, particularly by providing patients, as swiftly as possible, with innovative and reliable products and through increased market surveillance thanks to a strengthening of procedures. -to complete the internal market in pharmaceutical products taking account of globalisation and to establish a regulatory framework that favours the competitiveness of the European pharmaceutical sector. -to meet the challenges of enlargement. -to rationalise and simplify the system, improving transparency. The scope of the centralised procedure for medicinal products for human use still includes categories of products for which the procedure is obligatory and those for which it is optional. The procedure remains obligatory for products resulting from biotechnical processes, in particular those using recombinant DNA technology. The main amendment proposed seeks to make this procedure also compulsory for any new active substance appearing on the Community market. The procedure is optional for other products that constitute therapeutic innovation. Also, it is proposed to allow access to this procedure for medicinal products which, though innovative, may be of benefit if they are authorised from the outset at Community level. This may apply in particular to products that cannot be supplied without prescription. Member States have the option of authorising at national level the generic form of medicinal products authorised by the Community, on the condition that the harmonisation obtained at Community level is maintained. The manufacturers of these generic forms would henceforth have the choice between the two existing procedures (centralised and decentralised) for obtaining market authorisations. Other changes include: -two new ways of obtaining market authorisation. The applicant may apply for an accelerated assessment and decision, which has priority over other procedures. This refers particularly, but not exclusively, to products to treat cancer and HIV. The other procedure deals with the granting of a provisional authorisation of one year, subject to strict conditions and annual reassessment. -the five-yearly renewal of market authorisations is abolished. -Any authorisation not resulting in the actual marketing of the product concerned during two consecutive years ceases to be valid. -the Agency has additional tasks e. g, increasing the scientific advice it provides for companies at the research and development phases, before market authorisation procedures; participation in programmes for the compassionate use of human medicinal products; increased responsibilities regarding international scientific cooperation; and a procedure for solving potential conflicts with other bodies outside the field of product evaluation. The Agency's administrative and scientific structures are also modified. The changes are made with a view to enlargement and aim to adapt the composition of the Committees.