

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

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The committee adopted the report by Rosemarie MÜLLER (PES, D) amending the proposal under the codecision procedure (1st reading). The main amendments were as follows: - the name of the agency should be simplified, and the committee therefore proposed 'European Medicinal Products Agency' (EMPA); - the scope of the regulation should not be extended, as the Commission was proposing, so as to make it compulsory for all medical products for human use containing new active substances to be authorised centrally in future rather than on a national basis; the committee therefore deleted the new point which the Commission had added to the Annex; - there should be a scheme for establishing a European price for centrally authorised medicinal products; - 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; - where a new medicinal product submitted for authorisation is intended for paediatric use, the application should state that it has been tested for suitability for children; - the proposed database on medicinal products should also include information about which medicinal products are specifically authorised for administration to children; - assessment procedures should be speeded up, by reducing decision-making deadlines; - to ensure that the competent authorities are fully independent, there should be public funding of activities relating to pharmacovigilance, the operation of communications networks and market surveillance; - not only specialists but also patients should be able to notify any adverse reactions; - 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'; - the committee introduced a number of measures aimed at ensuring greater transparency and public access to information, including ensuring that labels and package leaflets are written in simple clear language comprehensible to the public; - when evaluating a medicinal product, the Agency's scientific committees should establish contact with patients' representatives to take account of their experience in the relevant field; - with regard to the composition of the management board and the appointment of the Executive Director of the EMPA, the same rules should apply as for the European Food Safety Authority.