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

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In approving the Commission's proposal relating to the authorisation of pharmaceutical products, MEPs adopted a number of amendments, particularly designed to improve transparency and access by consumers to, in particular, information on new drugs. The report drafted by Mrs Rosemarie MULLER (PES, D) was adopted subject to amendments. These amendments are laid down in the decision of the committee responsible (please refer to the summary dated 02/10/02). In general, the Parliament is of the opinion that the existing 1989 directive designed to provide this is not working and that people using new drugs should be guaranteed access to new information on the product as quickly as possible. MEPS want the Commission to report as soon as possible on the workings of this directive. Parliament wants to see a databank providing neutral information on drugs enabling comparisons between different products to be made. This should also include specific effects relating to children and be publicly accessible free of charge to all EU citizens. All drugs given to children should be fully tested, MEPs believe. Furthermore, Parliament wants more women to take part in clinical trials. Parliament also voted for another amendment seeking to oblige pharmaceutical companies to provide a leaflet on every new drug within 5 years of its being placed on the market, carrying the description "Newly authorised medicinal products. Please notify any adverse reactions". MEPs also want to see more incentives for the industry to develop new drugs to combat diseases caused by poverty. The main amendments were as follows: - 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 suveillance; - create further incentives to carry out research into medicinal products against widespread tropical diseases; - the Commission should submit as soon as possible a report on the implementation of Directive 89/105/EC and proposals for its revision and enforcement. This Directive relates to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems provides for rapid patient access to new medicinal products, fixing the maximum duration of negotiations on prices and reimbursement at 180 days; - in the case of innovative medicinal products which can be used to treat incurable diseases, the Agency shall lay down a streamlined procedure with a view to making such medicinal products available as quickly as possible; - 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; - introducing 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. The House also stated that provision should be made for a derogation for SMEs so that the cost of marketing the medicinal products developed by these enterprises can be kept

within reasonable bounds. The Commission should draw up, as a matter of urgency, a specific regulation aimed at resolving the problems concerning the availability of medicinal products for veterinary use and should in particular introduce a policy for 'orphan' medicinal products for veterinary use analogous to that established for human medicinal products. Such a Regulation should create the necessary mechanisms to ensure that all needs are covered by at least two therapeutic alternatives in the European Union, with the objective of guaranteeing both competition and the diversity of available protection options and thereby preventing the emergence of resistance. The Commission should submit a proposal within six months after the adoption of the present Regulation. With regard to the Agency's budget, it should be composed of fees paid by the private sector and contributions paid out of the Community budget to implement Community policies. On the basis of a duly reasoned request the Committee for Human Medicinal Products may require the duration of the scientific and clinical trials to be extended. The request must stipulate the additional length of time needed for the scientific and clinical trials to be carried out successfully. The request must be drawn up at least 15 days before the end of the period of scientific and clinical trial. The Agency shall publish an annual report on the recorded reactions and point out further research requirements.