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

2001/0252(COD) - 29/09/2003 - Council position

The common position, adopted by qualified majority, with the Belgian and Dutch delegations voting against and the German delegation abstaining is consistent with the aims of the Commission's proposal. It adopts 29 of Parliament's amendments adopted at first reading and accepts 68 in principle. Apart from changes introduced following amendments by the European Parliament and other changes on substance, the Council has agreed on a certain number of changes in order, in the first place, to clarify the provisions of the text, update terminology and to align the human and veterinary provisions to the largest extent possible. The more substantial changes are described below. - The Council has simplified the name of the European Agency for the Evaluation of Medicinal Products to "European Medicines Agency". - The Council has delineated the extension of the compulsory use of the centralised procedure to medicinal products for human use containing a new active substance for the treatment of 4 key disease areas (HIV /AIDS, cancer, neuro-degenerative disorders and diabetes). These disease areas are, in addition, broadly aligned with the areas in which specialist expertise is being developed at the Agency with the introduction of therapeutic advisory groups (which are now to be called scientific advisory groups). - In reaching agreement, the Council, in particular, had regard to the importance of maintaining national expertise for the evaluation of new active substances and the fact that existing legislation already allows the applicant to choose the centralised authorisation procedure for all medicinal products containing a new active substance. This option has been maintained for those products containing a new active substance that are not covered by paragraph 3 of the Annex. - In addition, the Council has inserted a review clause which will provide for the possibility to extend the range of products for which use of the centralised procedure is compulsory four years after the entry into force of the Regulation. The Council considers it appropriate to set out an ad hoc procedure for adoption of such decisions based on the Council's right to reserve implementing powers to itself in accordance with Article 202 of the Treaty. According to this procedure, the Commission may after consultation of the Agency, submit a proposal to the Council that shall act with a qualified majority. - For veterinary medicinal products, the Council has chosen to retain the applicants possibility to choose between the centralised procedure and the decentralised procedure to take account of the considerable regional differences in markets and disease patterns, e.g. animal species that only live in a limited part of the Community and some diseases only occurring in some geographical regions in the Community. In this context Article 79 should be borne in mind, which offers incentives to use the centralised procedure for veterinary products in order to improve availability. In addition, the "cascade" procedure set out in Directive 2001/82/EC is aimed at securing availability of veterinary products. - The provisions on the choice of Committee procedure in relation to decisions concerning marketing authorisations have been changed as the Council does not consider it consistent with Decision 1999/468 /EC to have two different procedures fordecisions having the same object. The Council believes that the management procedure is the appropriate procedure to apply for these decisions. - The Council has provided for the possibility of adopting amendments to the arrangements concerning the periodic safety update reports through a Committee procedure in the light of experience gained. Article 59 on the setting up of an Advisory Board has been deleted. - In view of the changes agreed to the composition of the Management Board, there is no need for an Advisory Board. - The provisions of Title IV, in particular Chapter 2, have been amended and rearranged to take full account of the adoption of the Council Regulation of 18 June 2003 amending Regulation 2309/93/EEC as regards the financial rules governing the Agency. - As concerns Article 82 on the principle of one single authorisation for a medicinal product, the exemptions from that rule have been clarified and now explicitly include the admission of more than one application for co-marketing reasons. - A number of changes have been made to Article 83 on compassionate use. Article 5 of Directive 2001/83/EC allows Member States to make unauthorised

medicinal products available to individual patients under the direct responsibility of a health care professional, e.g. for compassionate use reasons. The Council has considered that this provision should not be affected by this Regulation and has therefore chosen to provide for a complementary system based on making products available to groups of patients, and also made it clear that compassionate use can not be used by pharmaceutical companies as an alternative to applying for and obtaining a marketing authorisation. The paragraph on payment in relation to compassionate use products has been deleted as the Council believes that, in line with the principle set out in Article 1 (2), it should be up to each Member State to decide on the arrangements for the financing of the distribution of compassionate use products. Other changes include: - Adding a the possibility for Member States to ask for an opinion of the scientific committees, subject to the discretion of the relevant committee; - Adjusting some time limits in relation to the evaluation procedure; - Strengthening the supervision of the Agency by providing it with the explicit right to request the submission of data from the marketing authorisation holder at any time; - Extension of the duty of the marketing authorisation holder to report adverse reactions occurring in the territory of a third country; - Clarification of the wording of Article 37, including the alignment with the Annex (consistent use of the term "performance enhancers"). On the amendments of the European Parliament accepted partly or in principle, these refer to the following : - relative effectiveness; - the name of generic medicinal products; - benefit-risk analysis; - opinions of the Scientific Committees in the context of the mutual recognition procedure; - good clinical practice and clinical trials; - the exceptions from the principle of single name; - Directive 89/105/EEC on national procedures for the pricing and reimbursement of medicinal products; - conditions and restrictions in relation to the safe and effective use of medicinal products. However, as these conditions and restrictions should also be applied to third parties, the Council is of the opinion that a specific legal instrument is necessary to produce this effect. Therefore, Article 127a of Directive 2001/83/EC and 95a of Directive 2001/82/EC provides for adoption through comitology of decisions requiring Member States to implement such conditions and restrictions, including vis--vis third parties. Moreover, the Council considers it appropriate to use the term "recommendations" instead of "details" and to simplify the wording of the provision; - the accelerated procedure for the evaluation of certain medicines; - assessment reports; - the marketing authorisation holders' obligation to provide data on adverse reactions upon request to the European Medicines Agency; - the reference to Regulation 1049/2001/EC on access to documents. The Council has agreed on a new Article 73 which sets out that the aforementioned Regulation shall apply to documents held by the Agency; - authorisation of medicinal products under exceptional circumstances; - the accuracy of the documents and data submitted by the applicant; - setting out the same date protection period for medicinal products for human use authorised centrally as for products authorised nationally, except for those products where the use of the centralised procedure is compulsory. In coming to agreement on the issue of data protection, the Council has considered both the need to harmonise the widely differing data protection periods available in the Member States and the period of 10 years' data protection currently available to products using the centralised procedure. The Council therefore has decided that it is appropriate to retain the current 10 year's data protection for products for which use of the centralised procedure is compulsory. Furthermore, the Council has considered that offering an additional year's data protection for such products will be in line with encouraging innovation for these products. For products authorised nationally, the Council has considered that harmonising the period at 10 years would be difficult for some Member States but that a provision as the one agreed by Parliament, that allows generic companies to undertake all development work in the last two years of a ten year period (the "8+2" provision) would be acceptable. The Council felt that in view of the significant increase in data exclusivity that the "8+2" provision would be offering in a number of Member States, there was no justification for adding a further year's data exclusivity for nationally authorised products.