



COMMISSION OF THE EUROPEAN COMMUNITIES

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2001/0252 (COD)  
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2001/0254 (COD)

**OPINION OF THE COMMISSION**

**pursuant to Article 251 (2), third subparagraph, point (c) of the EC Treaty,  
on the European Parliament's amendments  
to the Council's common position regarding the  
proposals for a**

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**laying down Community procedures for the authorisation, supervision and  
pharmacovigilance of medicinal products for human and veterinary use and establishing  
a European Medicines Agency**

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Directive 2001/83/EC on the Community code relating to medicinal products  
for human use**

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**amending Directive 2001/82/EC on the Community code relating to veterinary medicinal  
products**

**AMENDING THE PROPOSAL OF THE COMMISSION  
pursuant to Article 250 (2) of the EC Treaty**

2001/0252 (COD)  
2001/0253 (COD)  
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#### **1. INTRODUCTION**

Article 251(2), third subparagraph, point (c) of the EC Treaty provides that the Commission is to deliver an opinion on the amendments proposed by the European Parliament at second reading. The Commission sets out below its opinion on the 34 amendments proposed by Parliament.

#### **2. BACKGROUND**

Proposal sent to the Council and the European Parliament  
COM(2001) 404 final – 2001/0252 (COD) – 2001/0253 (COD) –  
2001/0254 (COD)

26 November 2001

Opinion of the European Economic and Social Committee

18 September 2002

Opinion of the European Parliament – first reading

23 October 2002

Amended proposal sent to the Council and the European Parliament COM(2002) 735 final – 2001/0252 (COD)	12 December 2002
Amended proposal sent to the Council and the European Parliament COM(2003) 163 final – 2001/0253 (COD) and 2001/0254 (COD)	24 April 2003
Council common positions	29 September 2003
Commission Communication on the common position	7 October 2003
Opinion of the European Parliament – second reading	17 December 2003

### **3. OBJECTIVE OF THE PROPOSAL**

Regulation 2309/93 makes provision for the evaluation of the Community procedures for the authorisation and supervision of medicinal products which entered into force in 1995. In the light of the experience acquired from 1995 to 2000, and the Commission's analysis in its report "on the operation of the procedures for granting marketing authorisations for medicinal products" (COM(2001) 606 final, 23.10.2001), it appeared necessary to adapt Regulation 2309/93 and Directives 2001/83/EC and 2001/82/EC on the Community codes relating to medicinal products for human use and for veterinary use.

Generally speaking, four main objectives are particularly relevant:

- (1) to guarantee a high level of public health protection, particularly by providing patients, as swiftly as possible, with innovative and reliable products and by increasing market surveillance by reinforcing monitoring and pharmacovigilance procedures;
- (2) to complete the internal market in pharmaceutical products while taking account of the implications of globalisation, and to establish a regulatory and legislative framework that favours the competitiveness of the European pharmaceuticals sector;
- (3) to meet the challenges of the future enlargement of the European Union;
- (4) to rationalise and simplify the system, thus improving its overall consistency and visibility, and the transparency of procedures

Lastly, with regard to veterinary medicinal products, the proposals intend to specifically address the problem of availability of such medicinal products.

### **4. COMMISSION'S OPINION ON THE EUROPEAN PARLIAMENT'S AMENDMENTS**

#### **4.1 General assessment**

The Commission can accept in full the 32 amendments to the Council's common position adopted by Parliament on the proposal for a regulation, the 30 amendments to the Council's common position adopted by Parliament on the proposal for a directive on medicinal products for human use and the 22 amendments to the Council's common position adopted by Parliament on the proposal for a directive on veterinary medicinal products.

The Commission notes the convergence of views between the three institutions on the general approach and on the most important issues regarding the compulsory field of application of the centralised procedure, the administrative structure of the agency, the period of data protection, definitions, information for patients and the assessment of the environmental impact. Parliament's amendments make certain changes and clarifications to the Council's common position, which are nevertheless consistent with the objectives and general principles on which the Commission's proposals are based.

## **4.2 Analysis of the second reading**

The amendments adopted by Parliament mainly concern the issues of the compulsory field of application of the centralised procedure, the period of data protection and the administrative structure of the agency as far as the regulation is concerned, and the definitions, period of data protection, information for patients and assessment of the environmental impact as regards the two directives on medicinal products for human use and veterinary use.

### ***4.2.1 Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.***

#### **- Compulsory field of application of the centralised procedure (amendments 44, 56 and 63):**

Parliament has requested an extension of the compulsory field of application of the compulsory centralised procedure. The Council's common position provided for application of the procedure to new medicinal products for the treatment of four diseases, namely AIDs, cancer, diabetes and neurodegenerative disorders. Parliament added a fourth category, orphan medicinal products pursuant to Regulation (EC) No 141/2000 of the European Parliament and of the Council. It also provided that four years after entry into force of the Regulation, the procedure would also obligatorily cover new medicinal products for the treatment of auto-immune diseases and other immune dysfunctions and viral diseases. A revision clause with an ad hoc procedure is also provided for. The Commission considers that the proposed amendments would significantly strengthen application of the authorisation procedure and allow greater accessibility to new medicinal products throughout the Community.

#### **- Administrative structure of the agency (amendments 59 and 60):**

The amendments proposed by Parliament aim to strengthen, on the one hand, the provisions on the appointment of members of the scientific committees and, on the other, the provisions on the composition of the Management Board. For the scientific committees, Parliament introduces the obligation for the Member States to consult the Management Board before finalising the appointment procedures for these committees. Parliament wishes in this way to give the Management Committee of the Agency the possibility of influencing the composition of the committees in order to guarantee the presence of sufficient experts to cover the various scientific fields for the evaluation of medicinal products. As regards the Management Board, Parliament wants its composition also to include representatives of Parliament itself and, in particular, representatives of civil society, patients, doctors and veterinary surgeons.

The Commission believes the proposed amendments are on the right lines and are a good compromise, suiting the needs of both management and the scientific assessment of medicinal products.

- Period of data protection for medicinal products authorised under the centralised procedure (amendments 12 and 62) :

The amendments proposed by Parliament provide for the same period of data protection for products authorised under the centralised procedure whether application of the procedure is compulsory or optional. The period provided for is eight years of data protection and two additional years of marketing protection. Products which refer to the data after the eight years of protection cannot be marketed for two years after the end of that period. Furthermore, medicinal products for which one or more new therapeutic indications of significant clinical benefit compared with existing therapies are authorised during the eight-year period may receive one additional year of protection.

Parliament also approved a new provision which will clarify the application over time of the provisions concerning data protection. These new periods will apply only for reference medicinal products for which applications for authorisation are made after the date on which the new provisions enter into force. The Commission considers this provision particularly important in the context of the new Member States, which have to bring their national provisions into line with the new legislation.

- Other amendments making the text clearer and more specific and strengthening its provisions

- amendments 1, 41, 42 and 43 clarify aspects of the recitals concerning small and medium—sized enterprises, tropical diseases, budgetary provisions and the application of patent law;
- amendments 11, 47, 48, 50, 52, 53, 55 and 37 strengthen the provisions on transparency and the general public's access to documents;
- amendments 31, 32 and 33 make specific reference to the Committee on Herbal Medicinal Products;
- amendments 57 and 58 concern the databases and explain their content;
- amendments 8 and 18 concern the areas of competence of the scientific committee in the event of arbitration, amendment 45 the requirements for clinical trials carried out outside the Community, amendment 46 the duration of the analysis by the Committee, amendment 49 and amendment 54 the frequency of PSURs (periodic safety update reports), amendment 51 the file to be submitted for the five-year renewal and amendment 61 the pharmacovigilance tasks of the agency and the communication networks.

The Commission accepts these amendments, which do not alter the objective of the proposal but strengthen some of the existing provisions.

**4.2.2 Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use and Directive amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.**

- Definitions (amendments 60, 61, 63, 65, 58 and 67 of the human code and 37, 39, 40, 35 and 44 of the veterinary code):

Parliament wished to amend the definitions of medicinal product, generic medicinal product and biosimilar medicinal product and to specify the conditions in which the definitions were applicable. It also specified the clause applicable in the case of borderline products, for which it is not possible precisely to determine which set of rules applies.

In the Commission's view these amendments clarify the provisions concerned and are therefore acceptable.

- Period of data protection (amendments 14, 68 and 62 of the human code and 38 of the veterinary code) :

Parliament adopted amendments to bring the period of data protection into line with the period applicable to products authorised under the centralised procedure (see above, point 4.2.1).

- Information for patients (amendment 77):

Parliament inserts a provision obliging the Commission to adopt a report on the situation in the Community regarding the information provided for patients on medicinal products available on prescription only. On the basis of that report, the Commission would state whether it considers it appropriate to make changes to the current rules applicable to those products.

The Commission accepts this amendment; future proposals on this subject will thus be based on facts and patients' real needs regarding information.

- Environmental impact of the authorisation of medicinal products (amendments 56, 64, 57, 75 and 84 of the human code and 34, 5, 43, 49 and 53 of the veterinary code) :

Parliament adopted amendments to strengthen obligations regarding the assessment of the effects on the environment that the authorisation of medicinal products may have and the measures to be taken to offset these effects. It also introduced a distinction between medicinal products for human use, for which the assessment of these effects cannot be included in the final assessment of the risk/benefit balance, and veterinary medicinal products, for which the assessment of these effects must be taken into account when the risk/benefit balance of the product is assessed.

The Commission accepts these amendments, particularly because they respect the difference between the two types of medicinal product – those for human use and those for veterinary use.

- Other amendments making the text clearer and more specific and strengthening its provisions:

- as regards the human code, the Commission accepts amendment 66 on clinical trials, amendment 69 on the application of the mutual recognition procedure to homeopathic medicinal products, amendment 70 on assessment deadlines, amendment 25 on the justification for approved indications, amendment 72 on conditional marketing authorisations, amendment 73 on international non-proprietary names, amendment 74 on the space to be provided on the packaging to indicate the prescribed dose, amendment 76 on information in Braille, amendment 83 on the provision regarding continued supplies, amendment 59 on the funds earmarked for pharmacovigilance, amendment 78 on the frequency of PSURs (periodic safety update reports), amendments 79 and 80 bringing the text into line with the regulation concerning tests carried out by an Official Medicines Control Laboratory and amendments 81 and 82 on transparency and public accessibility;
- as regards the veterinary code, the Commission accepts amendment 45 on the application of the mutual recognition procedure to homeopathic medicinal products, amendment 46 on assessment deadlines, amendment 48 on the space to be provided on the packaging to indicate the prescribed dose, amendment 36 on the funds earmarked for pharmacovigilance, amendment 54 on the frequency of PSURs (periodic safety update reports), amendments 52 and 51 bringing the text into line with the regulation concerning tests carried out by an Official Medicines Control Laboratory, amendments 41 and 42 adding the full reference of Commission Decision 2000/68/EC establishing the identification of equidae for breeding and production, amendment 11 concerning the withdrawal period for homeopathic medicinal products intended for food-producing animals the active substance of which is listed in Annex II to Council Regulation (EC) No 2377/90 and amendment 47 concerning the documents to be submitted for the five-year renewal of marketing authorisations.

The Commission accepts these amendments, which do not alter the objective of the proposal but strengthen some of the existing provisions.

## **5. CONCLUSION**

Pursuant to Article 250(2) of the EC Treaty, the Commission amends its proposal as set out above.