COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 13.3.2006
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2004/0217(COD)

# COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

**pursuant to the second subparagraph of Article 251 (2) of the EC Treaty**

**concerning**

**the common position of the Council with a view to the adoption of a regulation on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004**

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**(Text with EEA relevance)**

## 1. BACKGROUND

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| Transmission of the proposal to the Council and to the European Parliament - COM(2004) 599 final – 2004/0217 (COD) | 22 October 2004 |
| Date of opinion of the European Economic and Social Committee | 11 May 2005 |
| Date of opinion of the European Parliament - first reading | 7 September 2005 |
| Date of transmission of the Amended proposal COM(2005) 577 | 10 November 2005 |
| Date of adoption of the Council common position | 10 March 2006 |

## 2. OBJECTIVE OF THE COMMISSION PROPOSAL

The initial proposal aimed to address the current situation in Europe whereby more than fifty percent of the medicines used to treat children have not been tested and are not authorised for use in children. The health and therefore quality of life of the children of Europe may suffer from a lack of testing and authorisation of medicines for their use. The overall policy objective was to improve the health of the children of Europe by increasing the research, development and authorisation of medicines for use in children. General objectives were to:

(1) increase the development of medicines for use in children;

(2) ensure that medicines used to treat children are subject to high quality research;

(3) ensure that medicines used to treat children are appropriately authorised for use in children;

(4) improve the information available on the use of medicines in children, and;

(5) achieve these objectives without subjecting children to unnecessary clinical trials and in full compliance with Community legislation on clinical trials (Directive 2001/20/EC[1]).

## 3. COMMENTS ON THE COMMON POSITION

### 3.1. Overall remarks on the common position

The common position has been adopted by the Council by qualified majority.

To a very large degree the common position is in line with the Commission's amended proposal. In addition it introduces a small number of changes to the Commission's amended proposal which improve the text while maintaining the initial objectives of the Commission. Many of these modifications concern improvements in the layout of the text or constitute editorial improvements which do not change the meaning or practical application of the Regulation.

Key amendments proposed by the European Parliament in the first reading, such as transparency and membership of the Paediatric Committee, transparency of clinical trials in children, provisions in the event of discontinuation of medicines, funding for studies, labelling of medicines, clearer timelines for procedures, deadlines for the implementation of the regulation, avoiding double rewards and clarifying in what circumstances rewards will be granted, and on review of the paediatric regulation are present in the common position, sometimes with drafting changes to ensure the legal consistency of the text and technical workability of the measures and procedures put in place.

### 3.2. European Parliament amendments included in full, in part or in principle in the amended proposal and incorporated in full, in part or in principle in the common position

The following amendments have been included in the common position, in some cases with modifications:

1 on suitable formulations and routes of administration, 2 on the aims of the Regulation, 4 on the circulation of safe medicinal products, 5 on the scope of testing in the paediatric population, 6 (1st and 3rd parts) on the members of the Paediatric Committee and the need to ensure benefit from studies in children, 7 on the timing of testing in the paediatric population, 8 on the timing of studies in children, 9, 56, 63 (2nd part) and 64 on a research programme into medicines for children, 10 on the role of the Paediatric Committee in compliance and in assessing safety, quality and efficacy of a medicine, 15 (1st part) on the use of the data on the clinical trials database to avoid unnecessary studies, 17 on taking account of international data, 18 (1st part) on unnecessary trials, 19 (part) on the inventory of therapeutic needs, 20 on the timing of setting up the Paediatric Committee, 21 on the composition of the Paediatric Committee and providing for the consultation of the European Parliament, 22 on opinions of the Paediatric Committee and their publication, 26 and 29 on the Paediatric Committee's tasks, 27 on a communication role for the Paediatric

[1] OJ L 121, 1.5.2001, p. 34

Committee, 28 on assessments performed in third countries, 31 on variations, 33 and 39 on Rapporteurs for the Paediatric Committee, 34 on the deadline to inform the applicant, 35 on the list of waivers, 40 (except the last part) on modifying a Paediatric Investigation Plan, 42 on Agency Decisions, 43 (1st and 2nd parts) on product information, 44 (1st part) on a European logo, 45 on which medicines should be labelled with the European logo, 46 (2nd part) on a register of marketing deadlines, 50 on product withdrawals, 52 (part) on the non accumulation of rewards, 55 on public access to the inventory, 57 on public access to details of trials in the European database, 58 on the guidance concerning the database of clinical trials, 62 and 69 on the type of studies to be considered by the Paediatric Committee, 66 on publication of the names of those infringing the regulation, 67 on the review of the operation of the Regulation and of the system of rewards and incentives. The Commission notes the divergence between the common position and the modified proposal on the timing and nature of the review. Although the Commission can support the common position in this regard it has a preference for the focus placed by the modified proposal on the six-year review.

### 3.3. European Parliament amendments not included in the amended proposal and not incorporated in the common position

The following amendments were neither included in the amended proposal nor incorporated in the common position:

3 and 16 on reordering the recitals, 6 (2nd part), 11 and 46 (1st and 3rd parts) on the deadline for placing on the market existing medicinal products newly authorised for children, 12 on a recital on a European paediatric form for the collection of data on medicinal products, 13 on a recital on the responsibility of the Paediatric Committee for risk management, 14 and 51 on the removal of the requirement for a medicinal product to be authorised in all Member States, 15 (2nd and 3rd part) on national clinical trials databases, 18 (2nd part) on rare congenital conditions, 19 in terms of reordering the articles and in terms of redrafting (other than on the inventory of therapeutic needs), 23 on the number of representatives of the Commission and of the Executive Director, 24 on interests in the pharmaceutical industry, 25 on the free nature of scientific assistance, 30 on on-going paediatric studies, 32 on the scope of the requirements, 36, 37 and 38 on the submission of paediatric investigation plans, 40 (last part) on deadline for the submission of an amended paediatric investigation plan, 41 on the detailed rules of interaction with the Paediatric Committee, 43 (3rd part) on the paediatric information contained in product information, 44 (2nd part) a European competition to design a logo to be used to label medicines for children, 47, 48, 49 and 83 on pharmacovigilance, 52 (part) on the exclusion of the extension of the supplementary protection certificate for products which have received a patent covering the same paediatric use in the EU, 53 on the number of extensions of the supplementary protection certificate, 54 on a simplified marketing authorisation procedure for orphan drugs, 65 on the harmonisation of national measures enacting penalties, 68 on the deadline for submission of an application for an extension of the supplementary protection certificate, 70 on transitional measures for paediatric investigation plans, 71 on the date of introduction of the requirements.

### 3.4. Other modifications introduced by the Council common position compared with the amended proposal

Recital 5 in the amended proposal was modified to delete the explicit reference to Article 95 of the Treaty. Although the Commission can accept this deletion, it should be noted that the legal basis for the paediatric regulation is Article 95 of the Treaty.

A new recital 38 was added to the common position on subsidiarity according to an inter-institutionally agreed text. The Commission supports this addition.

Article 2 in the amended proposal was modified in the common position to add a definition of a paediatric use marketing authorisation. This definition was moved from Article 31 of the amended proposal (renumbered as 30 in the common position).

Article 4 in the amended proposal was modified in the common position to specify that all members of the Paediatric Committee will have alternate members and that three members will represent healthcare professionals and three members will represent patient associations. The Commission does not object to these changes as it believes that the relevant expertise and balance of representation will be maintained.

Article 6 in the amended proposal was deleted in the common position as Regulation (EC) No 726/2004 already has strict rules for the European Medicines Agency committees as regards independence and interests in the pharmaceutical industry. Recital 8 was correspondingly strengthened with respect to the independence and interests of Paediatric Committee members. The Commission supports these changes as the independence and interests of the European Medicines Agency committee's are definitively dealt with in Regulation (EC) No 726/2004.

Article 7 in the amended proposal was renumbered as 6 in the common position and modified to include the additional task of the Paediatric Committee of recommending a symbol for the labelling of medicines indicated for children. Paragraph 2 of that article was amended in the common position to stipulate that the Paediatric Committee shall consider whether or not proposed studies can be expected to be of significant therapeutic benefit to an / or fulfil a therapeutic need of the paediatric population. The Commission does not object to this change.

Article 9 of the modified proposal was renumbered as 8 in the common position and modified to clarify that the requirements for the results of studies in children or an Agency decision on a waiver or deferral shall cover both the existing and the new indications, pharmaceutical forms and routes of administration. The Commission fully supports this change.

Article 16 in the amended proposal was renumbered as 15 in the common position and modified to clarify that Paediatric Investigation Plans related to the requirements of Articles 8 and 30 may be submitted for agreement. The Commission supports this change.

Article 18 in the amended proposal was renumbered as 17 in the common position and modified to state that the Committee shall consider whether or not the measures proposed to adapt the formulation of the medicinal product for use in different subsets of the paediatric population are appropriate. The Commission fully supports this change.

Article 24 in the amended proposal was renumbered as 23 in the common position and modified to clarify that when the applications are submitted in accordance with the procedure set out in Articles 27 to 39 of Directive 2001/83/EC, the verification of compliance, including, as appropriate, requesting an opinion of the Paediatric Committee, shall be conducted by the reference Member State. The Commission supports this change.

Article 25 in the amended proposal was renumbered as 24 in the common position and modified to clarify that incentives provided for in Article 38 would also not be granted in the event of non compliance detected during the scientific assessment. The Commission does not object to this change, however, it is noted that the provisions of Article 38 are pure incentives and not rewards for requirements.

Article 26 in the amended proposal was renumbered as 25 in the common position and modified to set the deadline at 10-days for the Agency to transmit the opinion of the Paediatric Committee to the applicant. The Commission supports this change.

Article 33 in the amended proposal was renumbered as 32 in the common position and modified to state that the package leaflet shall contain an explanation of the meaning of the symbol, to provide that the Commission select the symbol based on a recommendation from the Paediatric Committee and to clarify the transitional arrangements. Recital 17 in the amended proposal on the labelling of medicines for children was renumbered 18 in the common position and was amended to bring it in line with the revised article. The Commission supports this change as this will ensure the best use of the expertise of the Paediatric Committee.

Article 35 in the amended proposal was renumbered as 34 in the common position and modified to bring the definition of risk management system in line with current scientific knowledge. The Commission supports this change.

Article 40 in the amended proposal was renumbered as 41 in the common position and modified to clarify who would submit clinical trial results to the Agency. The Commission supports this change.

Article 41 in the amended proposal was renumbered as 42 in the common position and modified to set a deadline for the Paediatric Committee to provide guidance on the data to be collected by the Member States. The Commission supports this change.

Article 44 in the amended proposal was renumbered as 45 in the common position and modified to clarify that it is the Marketing Authorisation Holder that should submit any paediatric studies already completed, to clarify the competent authorities' role in updating product information. The Commission supports this change.

Article 45 in the amended proposal was renumbered as 46 in the common position and modified to clarify the competent authorities' role in updating product information. The Commission supports this change.

Article 50 in the amended proposal was deleted in the common position as the provision was judged to be unnecessary given the provisions of Article 11 of the amended proposal (Article 10 of the common position). The Commission supports this change.

Article 52 in the amended proposal was modified in the common position to: define 'application for an extension of the duration'; to clarify the procedures when Supplementary Protection Certificate applications are pending; to clarify the contents of an application for an Supplementary Protection Certificate extension and how to submit such an application; to clarify that extensions may be revoked if granted contrary to the provisions of the paediatric regulation and how this will occur; and, to clarify the appeals system. The Commission supports these changes.

Article 54 in the amended proposal was renumbered as 55 in the common position and modified to add a new task for the Agency to take decisions related to the operation of the paediatric regulation.

## 4. CONCLUSION

The Commission supports the common position.