Medicinal products for paediatric use

2004/0217(COD) - 10/03/2006 - Council position

The common position has been adopted by the Council by qualified majority. The European Parliament adopted 69 amendments to the proposal. 42 of these have been incorporated, either in full, in part or in principle into the Council's common position corresponding to around two thirds of the proposed amendments. 27 amendments have not been accepted. The common position incorporates most of the amendments proposed by the European Parliament accepted or accepted in principle by the Commission in its amended proposal.

The following amendments were amongst those that were **accepted** by the Council:

- the Paediatric Committee will be established within 6 months after the entry into force of the Regulation;

- the Paediatric Committee should appoint a rapporteur as part of the preparation of decisions on product specific waivers;

- the Council agrees to the amendments on updating and public availability of the list of waivers;

- the Council supports the principle of avoiding double rewards gained on the basis of the same research in the following particular situation. Directive 2001/83/EC as amended by Directive 2004/27/EC, provides that the period of market protection shall be extended by one year if the marketing authorisation holder obtains an authorisation for a new indication which is judged to bring significant clinical benefit in comparison with existing therapies. In the case of a new paediatric indication, this additional year of market protection should not be granted together with the six-month extension when based on the same research. To avoid this cumulative reward, the Council has introduced a new paragraph in the relevant Article.

The Council also accepted the following amendments in full, part or in principle;

- transparency of clinical trials in children;

- on the role of the Paediatric Committee in compliance and in assessing safety, quality and efficacy of a medicine;

- provisions in the event of discontinuation of medicines;

- funding for studies;

- labelling of medicines provisions;

- provisions on clearer timelines for procedures;

- deadlines for the implementation of the regulation, and on review of the paediatric regulation;

- on the use of the data on the clinical trials database to avoid unnecessary studies;

- on taking account of international data;

- on the composition of the Paediatric Committee and providing for the consultation of the European Parliament;

- on opinions of the Paediatric Committee and their publication,

- on a list of waivers on modifying the Paediatric Investigation Plan;

- on product information, on a European logo, on which medicines should be labelled with the European logo, on a register of marketing deadlines;

- on public access to details of trials in the European database;

- on publication of the names of those infringing the regulation;

- on the review of the operation of the Regulation and of the system of rewards and incentives.

European Parliament amendments **not incorporated** in the common position:

- the Council did not consider the Paediatric Committee to be primarily responsible for the ethical assessment of the Paediatric Investigation Plan. Ethical assessment of proposals for clinical trials is the primary responsibility of the Ethics Committees. The Council does not consider that members of the Paediatric Committee must have international-level experience and knowledge of the pharmaceutical industry.

- the Council decided to delete the amendment on independence and impartiality of the members of the Paediatric Committee, since detailed provisions on such requirements are already set out in Regulation 726 /2004, to which explicit reference is made;

- the Council supports the principle that the Committee should advise on communication about the conduct of clinical trials in children, but does not consider it appropriate for the Paediatric Committee to have a self-promoting function;

- the Council considers that the amendment opening a possibility to provide information on ongoing paediatric studies, is not necessary. The Commission proposal does not require the completion of all paediatric studies at the time of application for marketing authorisation. The “deferral” provision allows for delay in the initiation of paediatric clinical studies so as to ensure that the studies are only done when it is safe and ethical to do so. The Commission proposal also provides for the deferral decision to contain a timetable to complete the studies. The Council agrees with the Commission proposal in these respects;

- the Council agrees with the Commission proposal that provides for the summary report to be prepared by the Agency. This is consistent with the operating methods of the Committee on Orphan Medicinal Products. Ten days are inadequate for the preparation of the summary report by the Agency;

- the Council considers that it would be confusing for the patient and carer if some, but not all, products authorised for paediatric use were identified by a Community symbol on the label. The symbol, therefore, should apply to all medicinal products with a paediatric indication. In addition, the meaning of the symbol should be explained in the patient information leaflet and a deadline should be introduced for the application of the symbol;

- with regard to post-authorisation requirements, the Council supports the text of the Commission proposal which makes it clear that the legal obligation is to market within two years. In addition, existing EC pharmaceutical legislation sets out clear deadlines both for the granting of a marketing authorisation and

for national decisions concerning the pricing and reimbursement for medicinal products. The Council considers that it is inappropriate, therefore, to provide for derogations in the application of this provision in cases where competent authorities are unable to meet such deadlines;

- with risk management systems when the competent authority has cause for concern, the European Parliament proposed to make such a system compulsory. The Council recalls that the EC pharmaceutical legislation has recently been amended and now contains strengthened and new pharmacovigilance measures, including risk management systems. The proposed Regulation contains a provision for the competent authority, whenever it has cause for concern, to require a risk management system to be put in place. The Council does not find it appropriate to make this provision compulsory, as there may be occasions when such a requirement would add an unnecessary burden and may present a barrier to access to appropriate medicines.

The Council also **rejected** the following amendments:

- on the removal of the requirement for a medicinal product to be authorised in all Member States;

- a European competition to design a logo to be used to label medicines for children,

- 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,

- on the number of extensions of the supplementary protection certificate;

- on a simplified marketing authorisation procedure for orphan drugs;

- on the harmonisation of national measures enacting penalties;

- on the deadline for submission of an application for an extension of the supplementary protection certificate;

- on transitional measures for paediatric investigation plans

- on the date of introduction of the requirements.

The Council introduced **other modifications introduced by the Council** common position compared with the amended proposal.

- A recital was modified to delete the explicit reference to Article 95 of the Treaty.

- The Council states that, in analogy to what is the case for the Committee for Human Medicinal Products, it will introduce alternates for the members and specify the procedure for their appointment. In view of the introduction of alternates, the Council considers that six members are sufficient to represent the interests of healthcare professionals and patient associations. However, the Council considers that it should be made clear that three members should represent healthcare professionals and three members should represent patient associations. The list of disciplines represented on the Committee applies to the Committee as a whole and should be incorporated in the list of disciplines set out in the Regulation. The Commission did not object to these changes as it believes that the relevant expertise and balance of representation will be maintained.

An additional task of the Paediatric Committee is to recommend a symbol for the labelling of medicines indicated for children. The Paediatric Committee shall consider whether or not proposed studies can be expected to be of significant therapeutic benefit or fulfil a therapeutic need of the paediatric population.

The Council clarified that the requirements for the results of studies in children or an Agency decision on a waiver or deferral shall cover both existing and the new indications, pharmaceutical forms and routes of administration.

A modification states 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 Council clarified that when the applications are submitted in accordance with the procedure set out in 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.

Incentives provided for would also not be granted in the event of non compliance detected during the scientific assessment.

The Agency will have ten days to transmit the opinion of the Paediatric Committee to the applicant.

It is the Marketing Authorisation Holder that should submit any paediatric studies already completed, to clarify the competent authorities' role in updating product information.

Finally, the Council clarified: the procedures when Supplementary Protection Certificate applications are pending; the contents of an application for an Supplementary Protection Certificate extension and how to submit such an application; extensions may be revoked if granted contrary to the provisions of the paediatric regulation and how this will occur; the appeals system.