Medicinal products for paediatric use

2004/0217(COD) - 10/11/2005 - Modified legislative proposal

Following the first reading of the proposed Regulation in Parliament, the Commission has given its opinion on the Parliamentary amendments and modified its initial proposal accordingly.

The Commission has accepted eighteen amendments in their entirety. In summary, they relate to:

- Amendments highlighting that the objective of the proposal is to promote the circulation of safe medicinal products and that not all testing on children may be appropriate. A further amendment, accepted by the Commission, clarifies that studies on children may not always be possible prior to granting marketing authorisations for adults and that the provision for medicines for children should not delay marketing authorisation applications for medicines in adults. An amendment highlighting the role of the Paediatric Committee in checking compliance with the paediatric investigation plan and in giving an opinion on the safety, quality and efficacy of medicine in children was also accepted by the Commission.

- The proposed amendment which seeks to avoid unnecessary studies on children through the use of data on the clinical trials database.

- Further amendments acknowledged by the Commission and incorporated into the modified proposal include those highlighting the importance of taking international data into account when establishing and operating a European clinical trial network, clarifying that children should not be subjected to any unnecessary trials, (be they clinical or other) and an amendment clarifying that the opinion of the Paediatric Committee will be adopted by a majority of members, with the divergent views being published for public scrutiny.

- Other amendments relating to the Paediatric Committee and adopted by the Commission refer to the appointment of a rapporteur for the Committee and an amendment ensuring that the list of waivers are regularly updated and made available to the public.

- Also accepted are amendments proposing the establishment of a European logo for paediatric medicines and that existing paediatric medicines authorised for children should be labelled with the that logo.

- An amendment establishing a publicly accessible register indicating the deadline for placing newly authorised products for children on the market.

- The last two amendments accepted by the Commission ensure that the scope of Commission guidance concerning the database of clinical trials includes what information should be made public and how the Agency should achieve this and clarifying that ongoing, as well as, completed studies should be taken into account by the Committee when assessing paediatric investigation plans, waivers and deferrals.

Those accepted by the Commission in part or in principle refer, *inter alia*, to amendments:

- Concerning the independence and requirements in terms of professional experience of the members of the Paediatric Committee and the need to ensure that any studies in children have potential significant therapeutic benefits for them. The Commission suggests that a rewording is necessary to clarify that the members of the Committee must have experience relevant to the work

of the Committee – but that this experience may have been gained other than in the pharmaceutical industry. In addition, the Commission has changed the wording in order to clarify that, when the Paediatric Committee considers the potential significant therapeutic benefits of a medicine, these potential benefits relate to either the patients to be included in studies or the paediatric population at large.

- Intended to clarify that, in some circumstances, it is not appropriate to conduct studies in children in parallel with adult studies. The recital has been reworded to specify the mechanisms foreseen in the Regulation (waivers and deferral) to address such a situation.

- Providing for the establishment of a research programme into the paediatric use of medicinal products, which are not protected by a patent or supplementary protection certificate.

- Concerning the inventory of therapeutic needs. This has been partially reworded to provide for a longer deadline for publication. The survey will take two years to complete and the Paediatric Committee should be granted twelve months to carefully assess the data and adopt the inventory.

- Requiring the Paediatric Committee to be operational within six months from the date of entry into force of the Regulation. A reformulation of the amendment has been necessary to ensure that the deadline can be met.

- Broadening the composition of the Paediatric Committee and providing for the consultation of the European Parliament before the designation of the members appointed by the Commission. The Commission will be adding "general practitioners" to the list of those sitting on the Paediatric Committee.

- Concerning the Paediatric Committee's task as regards the inventory of therapeutic needs.

- Stating that the Committee must take account of results and assessments performed in third countries.

- Introducing a deadline for the Agency to adopt a Decision. The Commission, however, proposes a ten day deadline.

- Providing that, in cases where a company stops commercialising a product then the company must allow another company access to marketing authorisation. The Commission has reworded the amendment so that the periods of protection granted by the reward or incentive should have expired for this provision to apply. The Commission also considers it appropriate that those holding a market authorisation should be allowed to transfer their authorisation rather than relying on Article 10c of Directive 2001/83.

- Excluding an extension of the supplementary protection certificate for products which have received any form of data or market exclusivity for the same paediatric use in the EU. This has been done to avoid cumulative rewards.

- On the review of the operation of the Regulation. The review will include a public health assessment alongside an economic assessment.

Amendments not accepted by the Commission include, *inter alia*,:

- Those proposing to move the recital dealing with the survey, inventory and network to a new Chapter 1a.

- Those, that task the Paediatric Committee with the ethical assessment of paediatric investigation plans. The primary responsibility of the Committee will be scientific.

- Those aimed at introducing a flexible deadline for placing existing medicinal products which have been newly authorised for children on the market

- Those that want to remove the requirement for a medicinal product to be authorised in all Member States as a prerequisite for the extension of the supplementary protection certificate.

- Those making specific mention, in the Regulation's' objectives, of medicinal products intended for the treatment of rare congenital conditions suffered by children given that the Regulation applies to all paediatric populations and to all diseases suffered by children.

- Those that request the Member States to collect available data on existing uses of medicinal products and the drawing up of an inventory of therapeutic needs within a year.

- Those amendments providing that applications for agreement on paediatric investigation plans should include a summary report, reducing the deadline for validation of such applications by the Agency from 30 to 10 days and removing the deadline for industry to submit and discuss its plans for paediatric studies with the Paediatric Committee.

- Those aimed at creating a European competition to design a logo for paediatric medicines. The choice of the logo will require the expertise of specialists in paediatric medicines. Hence the modified proposal states that the Paediatric Committee will choose a new logo within one year of the Regulation's entry into force.

- Those that duplicate or amend some of the pharmacovigilance provisions contained in the Community pharmaceutical legislation.

- Those excluding an extension of the supplementary protection certificate for products whose active substance has already benefited from a patent covering the paediatric use or formulation, since this would run counter to the core objective of the proposed Regulation, namely stimulating research into paediatric medicines. However, and in line with the purpose of this amendment, the Commission does clarify that rewards associated with a completed Paediatric Investigation Plan should only be triggered by research completed after the Regulation has entered into force.

- Those reducing the deadline for submission of an application for an extension of the supplementary protection certificate since it takes approximately two years to conduct the necessary studies and to obtain a marketing authorisation for a generic product.

- Those introducing transitional measures relating to paediatric investigation plans. Applications submitted prior to the entry into force of the Regulation can not include findings from studies with agreed investigation plans since there will be no legal basis in pharmaceutical legislation or competent committee within the Agency to agree paediatric investigation plans in advance of the Regulation's entry into force.

- Those which seek to shorten the number of months from entry into force of the Regulation since they are considered unworkable.