Medicinal products for paediatric use

2004/0217(COD) - 29/09/2004 - Legislative proposal

PURPOSE: to improve the health of children in Europe by increasing the research, development and authorisation of medicines for use in children.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

CONTENT: the European Commission is proposing this Regulation following a Council Resolution, which called on the Commission to make regulatory proposals ensuring that new medicinal products for children and medicinal products already on the market are fully adapted to the specific needs of children. In order to fulfil this task the Commission has set out a number of objectives, which the proposed Regulation should fulfil, namely:

- To ensure that medicines used to treat children are subject to high quality research;

- To ensure that medicines used to treat children are appropriately authorised for use in children;

- To improve the information available on the use of medicines in children and;

- To achieve these objective without subjecting children to unnecessary clinical trials and in full compliance with the EU Clinical Trials Directive.

Until now, more than 50% of the medicines used to treat children in Europe have not been tested and are not authorised for use in children. Reluctance to test medicines on children has been cited as the main reason for this huge gap in authorised medicines for the paediatric population. The Commission suggests that this problem can be addressed by using the EU Directive on clinical trials, which lays down specific requirement to protect children who take part in clinical trials across the EU. Some of the key measures being proposed include:

- The creation of a paediatric committee. This will be responsible primarily for the assessment and agreement of paediatric investigation plans and requests for waivers and deferrals. Further, it may assess compliance with paediatric investigation plans and be asked to assess the results of studies. It will assess whether or not studies are unnecessary. At the same time it will avoid any delay in the authrorisation of medicines for other populations as a result of the requirement for studies in children.

- Marketing authorisation requirements. One of the central elements of the proposed Regulation is the introduction of a paediatric investigation plan. When drawing up the plan two principles need to be applied. Firstly, studies should only be conducted if there is a potential therapeutic benefit to children. Duplication of studies should be avoided. Secondly, that the requirements for studies in children should not delay the authorisation of medicines for other populations. Thus, unless a waiver or deferral has been granted, a paediatric investigation plan needs to be submitted at the time of application.

- Waivers from the requirement. The Paediatric Committee will draw up a list of waivers of specific medicinal products and classes of medicinal products. This will apply mostly to medicines being developed for adults, which are not needed to treat children.

- Deferrals from the timing or completion of studies in children. This will apply to studies in cases where some initial experience of a product has already been applied to adults or on studies, which might take longer in children than in adults.

- Marketing authorisation procedures. The procedures set out in existing pharmaceutical legislation are not altered by the proposal. It is being proposed that an application for a marketing authorisation including at least one paediatric indication based on the results of an agreed paediatric investigation plan will have access to the centralised Community procedure.

- The Paediatric Use Marketing Authorisation (PUMA). PUMA is being proposed as an incentive for off-patent medicines. It is a new type of authorisation. It will utilise existing marketing authorisation procedures but is specifically designed for paediatric medicine. Companies with a PUMA authorisation may continue using the brand name of their product – but in order to make it identifiable as a paediatric medicine the brand name will be followed a subscript of the letter P.

- Extension of the duration of the supplementary protection certificate. This is designed for new medicines and for products covered by a patent or a Supplementary Protection Certificate (SPA). It will only apply if all the measures included in the paediatric investigation plan are complied with, if the product is authorised in all Member States and if relevant information on the results of studies is included in the product – in which case the SPA can be extended for six months.

- Extended market exclusivity for orphan medicinal products. This is included in order to extend the ten-year period of orphan market exclusivity to twelve-years if the requirements for data on use in children are fully met.

- Paediatric study programme: Medicines Investigation for the Children of Europe (MICE). This measure is being introduced in order to offer funding for studies into the paediatric use of medicines not covered by a patent or a supplementary protection certificate.

- Information on the use of medicines for children. The Commission proposes extending the EudraCT database, which is designed to serve the purposes of the Clinical Trials Directive, by expanding the database to include all ongoing and terminated paediatric studies conducted both in the Community and third countries. Further, the Paediatric Committee will establish an inventory of therapeutic needs of children. European networks and clinical trial centres will be linked in a bid to facilitate co-operation and to avoid duplication of studies.

- Lastly, under the title "Other Measures" it is being proposed that the Paediatric Committee will be managed by the EMEA. Free scientific advice from the EMEA to sponsors for the development of medicines for children is also being proposed. The Regulation will put an additional burden on the EMEA and it is, therefore, being proposed that the Community subsidy to the EMEA be increased.

FIANCIAL IMPLICATIONS:

- Budget lines and headings: 02.040201 – European Agency for the Evaluation of Medicinal Products - Subsidy under Titles 1 and 2 - 02.040202 – European Agency for the Evaluation of Medicinal Products - Subsidy under Title 3.

- Overall figures: Total allocation for action (Part B): EUR 21 282 million for commitment.

- Period of application: 2007 to 2012.

- Overall multi-annual expenditure – commitment appropriations/payment appropriations: A total of EUR 21,282 for commitment appropriations and a total of EUR 21,282 for payment appropriations.

- Overall financial impact of human resources and other administrative expenditure:

Staff will be need for the Secretariat of the Paediatric Committee, Paediatric Investigation Plan applications, the Paediatric Research Network, Funding of studies and Support staff. The total foreseen for 2007 are 3, extending to 26 by 2012 and beyond.