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European Commission Proposal on Medicines for Children: Enough Incentives for Industry?

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The proposal for a regulation on medicinal products intended for paediatric use (http://dg3.eudra.org) adopted by the Commission in September 2004, is designed to increase the availability of medicines tested specifically for children. This article describes the key measures proposed (table 1).

In Detail

A new EMEA committee, with expertise in all aspects of the research, development, authorisation and use of medicines for children is central to the proposal and its operation. The committee will be responsible for the assessment and agreement of paediatric investigation plans and requests for waivers and deferrals. The proposal aims to integrate the development of medicines for children as an integral part of the development program for adults. To offer industry an incentive and reward for these studies, an extension of 6 months to the supplementary protection certificate has been foreseen. Secondly the proposal provides for the creation of a Paediatric Use Marketing Authorisation (PUMA) to establish a vehicle for providing incentives for off-patent medicines. A PUMA will utilise existing marketing authorisation procedures, but is specifically for medicinal products developed exclusively for use in children. PUMA applications will require data necessary to establish safety, quality and efficacy specifically in children, including any data needed to support an appropriate strength, pharmaceutical form or route of administration of the product, collected in accordance with an agreed paediatric investigation plan.

More Clinical Trials: Will Children be at Risk?

Although there may be concerns about trials in the paediatric population, there are also concerns about giving medicines to a population in which they have not been tested. The new EU Directive on clinical trials (see also ICU Management issue 1/2005 p6-8) lays down specific requirements to protect children who take part in clinical trials in the EU. The public health threat from daily use across the EU of untested medicines in children can therefore be safely addressed through the study of medicines for children, controlled and monitored through the existing EU Directive.

Are the Incentives Foreseen Sufficient?

The provision of the patent extension of six months reflects incentives legislated in the USA. However, is this the best way forward in Europe? In the EU, there is already a system in place to provide incentive for the development of less lucrative medicines for small populations, in the form of the Orphan Medicinal Product Regulation. The Committee of Orphan Medicinal Products at the EMEA has, in the four years during which it has been operational, received more than 305 applications and authorised more than 178 orphan medicinal products, including many for paediatric indications. This demonstrates the success of the existing provisions (Mc Clay 2004).

The responsible rapporteur at the European Parliament, Dr Peter Liese, believes that:

• the proposal should be improved with regards to the provisions concerning the out-of-patent drugs and academic research;

• the extension of market exclusivity for a longer period means that generics will enter the market later, and

• firms who do research may criticize the enforcing part of the Commission's proposal, since it obliges them to carry out additional work.

Another problem seems to be that for many life-saving medicaments the patent and data protections have already expired, so that extending market exclusivity for six months is no longer possible. According to Dr Liese, a solution would be the mobilisation of sufficient financial support. Another option would be obliging the pharmaceutical industry to finance trials on medicaments that no longer have patent or data protection. Despite these reservations, Dr. Liese (2005) has expressed the Parliament´s willingness to adopt the regulation quickly.

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