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EDITORIAL

Improving drug therapy for children in Europe

The proposed European regulation on medicinal products for paediatric use should be welcomed by both paediatric health professionals and parents. As outlined in the paper by Saint-Raymond and Seigneuret[1], the proposed legislation should result in an increase in the research and development of medicines for use in paediatric patients. Subsequently, fewer unlicensed and off-label medicines are likely to be used in children. As well as improving the authorisation of medicines, research should result in an increase in the evidence base for the use of medicines throughout the paediatric population.

The fact that legislation is being proposed is a tribute to the work of organisations such as the European Society for Developmental Pharmacology (ESDP) and the European Network for Drug Investigation in Children (ENDIC). These two groups have successfully argued for improved medicines in children, both within the medical and scientific profession and in society as a whole[2-4].

Although the proposal is to be welcomed, it is important that one recognises that market forces alone may not solve the problem of ensuring that the medicines that children need are always developed. The American legislation has been highly successful in ensuring more medicines are licensed for paediatric use[5]. Criticism has, however, been raised that the medicines studied are those that supply the greatest profits rather than answer the greatest needs of children[6]. It is to be hoped that the Paediatric Committee of the EMEA will ensure that the medicines studied are those that will provide the greatest benefit to children as opposed to the greatest profit to the pharmaceutical industry.

The biggest disappointment within the proposed legislation is the lack of funding for Medicines Investigation for the Children of Europe (MICE). The lack of a specific proposal for the funding of research and development of off-patent medicines in Europe is a major weakness. The creation of such a fund would enable academia and health professionals to study the medicines that are most likely to benefit children. It would be possible to successfully fund such a programme with a small percentage of the additional profits that will be made by the pharmaceutical industry with a six month patent extension[7]. Alongside more paediatric clinical trials, we also need more scientific research in different aspects of paediatric clinical pharmacology.

Despite this major weakness, the Commission's proposal needs the support of paediatric health professionals. Paediatric clinical pharmacologists and paediatric clinical pharmacists have shown that they are capable of working together on a European basis[3, 8-10]. Important initiatives such as the European Paediatric Clinical Trials Register (www.dec-net.org) will both help to ensure transparency and also greater involvement of the public[11]. It is important that paediatric health professionals continue to campaign for children to have the right to receive medicines that are scientifically tested for safety and efficacy prior to use.

Imti Choonara
Derbyshire Children's Hospital,
University of Nottingham, Derby, UK

Evelyne Jacqz-Aigrain
Robert Debré Hospital, Paris, France

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