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EDITORIAL

European legislation to improve medicines for children

The European Parliament and Council have passed Regulation Number 1901/2006 on Medicinal Products for Paediatric Use. The Regulation was published in the official journal of the European Union on 27th December 2006 and came into effect on 26th January 2007[1]. This legislation will hopefully improve drug therapy for the paediatric population. The aims of the Regulation are clearly stated.

- To ensure that medicinal products used to treat the paediatric population are subject to ethical research of high quality.
- To ensure that medicinal products are appropriately authorised for use in the paediatric population.
- To improve the information available on the use of medicinal products in the various paediatric populations.

These objectives need to be achieved without subjecting the paediatric population to unnecessary clinical trials[2].

The Regulation provides financial incentives to the pharmaceutical industry to study medicines in children. The pharmaceutical company has to propose and agree a paediatric investigation plan for an individual medicinal product with the European Medicines Agency (EMEA). Following completion of the studies in accordance with the agreed paediatric investigation plan, the pharmaceutical company will receive a six month extension of a patent or supplementary protection certificate for the medicinal product that has been studied. Medicines designated as orphan drugs may receive a two year extension to their marketing authorisation.

For older medicines not covered by a patent or supplementary protection certificate, it is still possible to agree a paediatric investigation plan. If successfully completed, the company can apply for a Paediatric Use Marketing Authorisation (PUMA). This would allow ten years of data protection[2].

An expert Paediatric Committee will be established by the EMEA. This Paediatric Committee will have the responsibility of ensuring that the *appropriate* medicines are studied. The financial incentives are considerable and the American experience has unfortunately shown that the pharmaceutical industry is happy to study medicines which are unlikely to be used extensively in paediatric patients, but are prescribed extensively in adults[3,4]. The EMEA, at a senior level, needs to ensure that the Paediatric Committee receives political support when they decline requests for the study of inappropriate medicines by the pharmaceutical industry.

A European register of clinical trials of medicinal products for paediatric patients consisting of all ongoing, prematurely terminated and completed paediatric studies will be established. It is reassuring that *part* of the information concerning paediatric clinical trials entered into the database, as well as details of the results of *all* paediatric clinical trials submitted to the regulatory agency will be made public. This is a key point within the Regulation and will help ensure that unnecessary clinical trials in paediatric patients are not duplicated. With the termination of the previous European paediatric clinical register (www.dec-net.org) this transparency is essential[5,6]. A database of paediatric clinical trials that was only accessible to the EMEA would not be beneficial for the children of Europe.

The Regulation is primarily aimed at the pharmaceutical industry and does not offer assistance for independent (academic or hospital) research. It is surprising that the European Parliament will not necessarily review the effects of the legislation in relation to the provision of medicines for children until 26th January 2013. The economic impact of the financial incentives will not be reviewed until 26th January 2017! Despite these limitations,

paediatric clinical pharmacologists and paediatric clinical pharmacists have a key role to play in ensuring that the Regulation results in more clinical trials in paediatric patients of all ages. These clinical trials need to be performed safely and effectively and involve medicines that will improve the management of illnesses within the paediatric population.

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