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Paediatric drugs - Who benefits from the European Paediatric Regulation?

Medicines in Europe Forum

The stated aim of the Paediatric Regulation (European Regulation (EC) No 1901/2006, adopted in 2006) was to encourage the development of drugs suitable for children (1). However, this Regulation was constructed with insufficient emphasis on children's needs.

It is true that the Paediatric Committee that was created within the European Medicines Agency (EMA) has been tasked with identifying children's unmet needs. But it is too often satisfied with producing inventories of drugs authorised for use in adults that are prescribed off-label for children in the various Member States, even though some of these practices are harmful to children (2).

The Paediatric Regulation focuses primarily on providing incentives for pharmaceutical companies that introduce paediatric forms of drugs already marketed for adults, or that market new drugs for paediatric use, even if these new drugs do not represent a therapeutic advance for children (2).

In September 2012, five years after the Regulation came into effect, the European Commission organised a public consultation to learn lessons from the experience acquired since its implementation (3).

Prescrire chose to respond to this consultation by detailing one example in France that illustrates particularly well some of the most lamentable aspects of the implementation of the Paediatric Regulation: the paediatric form of *losartan* (Cozaar°), an oral suspension for the treatment of hypertension in children (4).

The poorly-designed packaging for Cozaar° oral suspension is unsuitable and dangerous for children. This drug is difficult to obtain and is not reimbursable; furthermore, *losartan* is not the standard treatment for children with hypertension. Yet, in accordance with the Paediatric Regulation, the company that markets Cozaar° oral suspension was granted a 6-month extension to its market exclusivity in France on all forms of Cozaar°, even for its non-paediatric indications (4).

In its response, *Prescrire* also pointed out that the other component of the Paediatric Regulation, the paediatric-use marketing authorisation (PUMA), had not yet led to the development of any drugs that meet children's real needs (4).

Prescrire urged the EMA's Paediatric Committee to profoundly improve the implementation of the Paediatric Regulation, so that it better meets the needs of children, beginning with:

– Prioritising children's real therapeutic needs in the lists of "unmet paediatric needs", rather than simply producing inventories of existing practices without evaluating their appropriateness in children;

– Ensuring that drugs with paediatric indications represent a tangible therapeutic advance;

– Reducing the dangers to which children are exposed, by demanding improvements to the numerous packaging materials that are unsuited to paediatric use, starting with those that have already been implicated in medication errors and accidents (**a**)(1,4).

a- The Paediatric Regulation laid down a procedure for the reassessment of paediatric data on old drugs by the Paediatric Committee (Article 45 of ref 1). In practice, this procedure is mainly used to harmonise the paediatric information in the various national summaries of product characteristics, e.g. to add paediatric dosages or a statement that no data are available in children, as appropriate. Each year, 40 to 50 drugs are reassessed through this procedure (ref 4). Health authorities should use these reassessments to request improvements in the packaging of drugs with paediatric indications, to make them more suitable for paediatric use (ref 4).

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Prescrire's policy advocacy

In the field of health care, each policy decision has an influence on the conditions under which healthcare professionals practice and on patients' access to health care, factors which determine the quality and safety of patient care.

Changing the legislative framework for health products is a sensitive matter. It is certainly too sensitive to give free rein to vested interests or to adopt a short-sighted approach, which often put industry's short-term economic interests before public health.

That's why, for over 30 years, in addition to helping healthcare professionals and patients choose the most relevant treatment options, *Prescrire* has been working to improve health policy, first and foremost in the interest of patients. By analysing the strengths and weaknesses of the regulatory environment from the perspective of all parties that have a stake in health care: industry, health authorities, health insurance organisations, healthcare professionals, and patients. Together with other members of the International Society of Drug Bulletins (ISDB), *Prescrire* has been an active participant in international campaigns to increase the transparency and independence of drug regulatory agencies, public access to clinical trial data, etc.

Prescrire is an active member of the Medicines in Europe Forum (MiEF), which was founded in 2002, when the first drafts of the 2004 European legislative framework for medicinal products were proposed, to act as a counterbalance to the powerful pharmaceutical industry lobby.

We analyse draft laws and regulations in detail, anticipate and explain any potential dangers posed to patients or to the provision of health care and other social benefits, suggest alternatives, meet with members of parliament, highlight potential consequences to Member States' health ministers and European Commission departments (Directorates-General), and organise public debates. These sustained, rigorous campaigns often meet with success. For example, the tireless perseverance of *Prescrire* and other civil society organisations that have been campaigning over the past 10 years has prevented the European Commission from legalising direct-to-consumer advertising of prescription drugs in Europe.

These sustained campaigns, as well as other ad hoc actions, are an integral part of the socially responsible approach adopted by the health professionals who subscribe to and support *Prescrire*.