Medicines in Europe Forum

Open letter to Members of the Environment and Health Commission

Proposal for a regulation on medicinal products for paediatric use: Take the necessary time to improve an important project

"*Children shall have the right to such protection and care as is necessary for their well-being. (…) In all actions relating to children, whether taken by public authorities or private institutions, the child's best interest must be a primary consideration.* (…)" (Article 24 of the Charter of Fundamental Rights of the European Union).

Brussels, 18 April 2005

Dear Sir/Madam

The Medicines in Europe Forum welcomes the proposal aiming to make appropriate drugs available to children and to those treating them. However, the Forum believes that this proposal needs to be significantly amended for the regulation on medicinal products for paediatric use genuinely to meet the needs of children.

Why such haste? An in-depth discussion on the proposal for a regulation on medicinal products for paediatric use is vital, even if the Environment and Health Commission is currently busy considering other very important bills. Yet the Medicines in Europe Forum has noted that you will only have a few days to table amendments after the Commission has discussed the proposal. We feel this schedule does not allow sufficient time to introduce the necessary improvements to the proposed regulation.

Better than nothing? Some MEPs may be tempted to feel that this proposed regulation does not require much involvement on their part, because the regulation will be "better than nothing ". But in fact, it is untrue that there is currently "nothing" for children. Quite the opposite: there is a wealth of accumulated experience which we should start capitalising on in order to identify the true needs and priorities. The regulation should aim therefore not to be "better than nothing", but to be "better than what there already is".

Do better, at the best cost. The proposed regulation aims to offer additional incentives (paid for out of public funds) to pharmaceuticals firms to encourage them to fund more studies involving children. The cost of these incentives to society (the human cost associated with using children in clinical trials, additional operational costs for the European Medicines Agency, and funding the incentives) requires striking a scrupulous balance between the interests of the pharmaceuticals industry and children's best interests. Incentives for developing paediatric drugs are unacceptable unless they offer children genuine therapeutic benefits and particularly stringent pharmacovigilance measures are in place.

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This balance can only be achieved through:

1- a meticulous definition and evaluation of children's real needs;

2- the setting up of appropriate resources;

3- total transparency regarding the process;

4- active gathering of pharmacovigilance data;

5- rewards proportionate to the pharmaceuticals firms' efforts.

An escalation of "incentives" to drugs companies. If we take a detached look at the proposal for a regulation on medicinal products for paediatric use, we note that one of the European Commission's stated objectives is to give European pharmaceuticals firms the same advantages as American firms (where there is already a six-month monopoly extension to encourage firms to develop medicines for paediatric use). However, in times when drugs research and development is less fruitful, the firms increase their requests to extend their monopolies, claimed as incentives for concentrating on a particular therapeutic field.

In the United States, under the Bioshield Plan (against bioterrorism), pharmaceuticals firms are about to win the right to extend their monopoly on a drug of their choice for six months if they develop a new antibiotic, for example. Children today, antibiotics tomorrow, women or the elderly the next day…, to what extent can societies agree to give special funding to research that was previously part of the pharmaceuticals firms normal activity? How long will societies agree to extend monopolies on drugs that are becoming increasingly expensive?

The fact that the proposal for a regulation on medicinal products for paediatric use systematically grants an additional six-month monopoly for drugs (for both paediatric and adult use) irrespective of research and development costs and unrelated to the therapeutic benefits of the drugs, amounts to a blind allocation of public resources.

Take the time to improve the proposed regulation. The proposal for a regulation on medicinal products for paediatric use is an opportunity to respond better to the real needs of children. But for this regulation wholly to fulfil this objective, it requires significant improvement, over and above the proposals of the rapporteur. This requires you to take the time to analyse the issues, and to have sufficient time to table any amendments.

We are sure you will agree with us, and are counting on you.

Yours sincerely

The Medicines in Europe Forum

The Medicines in Europe Forum brings together several dozen patients groups, health professionals, consumers and social welfare organisations paying for medicines in a number of EU countries.

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