



## PAEDIATRICS MEDICINES REGULATION

### Briefing Paper for MEPS

Measure proposed	EGA Comments
<p><b>6 months extension of the SPC<sup>1</sup> / Patent for the <u>entire pharmaceutical product</u> to compensate for clinical studies in the on-patent sector<sup>2</sup>.</b></p>	<p><b>Comment</b> It may be reasonable to award an additional period of market exclusivity to compensate for the additional costs of obligatory paediatric trials. However, both the period of extension and the type of protection must be <u>proportional</u> to the cost and nature of the trials. The current proposal for a 6-month SPC/patent extension - based on the USA model - is also unnecessarily costly to healthcare budgets. Although it may be justified in a limited number of cases, where the costs are high and the revenues low, it would give disproportionate returns in cases where the clinical trial costs are low compared to the revenues generated.</p> <p><b>Recommendation - Proportionality and Transparency</b> More proportional measures should therefore be introduced which ensure that the period of SPC extension, if needed, is in proportion to the actual cost of the trial. Due to the expected high returns on adult medicines it is likely that only in exceptional cases would 6 months be needed - in cases where sales are low and trial costs high.</p> <p>Companies would be required to submit data on the costs of their trials and expected revenues. A precedent for this approach exists in the orphan medicinal products regulations<sup>3</sup>.</p>
<p><b>8+2 years exclusivity to cover paediatric indications in the off-patent sector as part of the granting of a PUMA (Paediatric Use Marketing Authorisation)<sup>4</sup></b></p>	<p><b>Comment</b> This measure could act as an incentive for developing <u>new paediatric formulations</u> where child populations are large enough to create a market. Assurance would be needed that the new paediatric formulation would be dispensed and reimbursed, to avoid off-label use of existing adult versions.</p> <p>In other cases, independently-funded studies will be necessary.</p>

<sup>1</sup> Supplementary Protection Certificate. Market protection for 20 year patents on medicinal products are increased by a further period of up to 5 years by the Supplementary Protection Certificate Regulation (1768/92/EEC).

<sup>2</sup> Article 36 of the proposed EC Regulation on medicinal products for paediatric use

<sup>3</sup> Regulation (EC) No 141/2000 of the European Parliament and of the Council, of 16 December 1999, on orphan medicinal products - article 3.1(a), and Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority' - article 2.2.

<sup>4</sup> Articles 31 and 38 of the proposed EC Regulation on medicinal products for paediatric use

## Explanatory Statement

In line with the EGA's previous support for the introduction of EU-wide measures to promote better use of medicines for children<sup>5</sup>, we welcome the European Commission's initiative to propose a Regulation in this area.

### 1. Role of the European pharmaceutical industry and independent research

All sectors of the pharmaceutical industry - together with independent research organisations - can play a role in maximising the benefits of medicines for children. For industry it will be important to be adequately compensated or be given incentives for developing new information or new formulations for child use. However, we also recognise that it would be unethical for industry to make excessive profits from these new provisions. Equally important is that the proposals ensure that trials on children be a "last resort" and that all other alternatives should first be exhausted - such as the assessment of current off-label use<sup>6</sup> and the results of existing trials outside the EU. In certain cases paediatric needs may not require new child formulations but the adaptation of current dosage regimes, smaller dosages of current products or simply better information for child use. The role of independent research in this area should also be recognised.

### 2. Costs to healthcare budgets

Member States should be aware that the costs to healthcare budgets of the proposed SPC extensions could be unnecessarily high. This is because of the consequent delays in the cost-savings that generic medicines and competition in the market can bring. It should be ensured that disproportionate returns for limited clinical trial costs are avoided. Amendments to the Commission's proposal are needed.

### 3. Off-patent sector

Whilst the Commission's proposed Regulation contains many helpful provisions to meet these objectives, the proposal does not reflect the fact that the off-patent sector has been identified as most in need of support for new investigations for children<sup>7</sup>. Moreover, the measures proposed are insufficient to fully adapt existing medicines for paediatric use.

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<sup>5</sup> On 18 February 2003 the EGA, Anne Ferreira, MEP and Minerva Malliori, MEP held a Round Table with paediatric specialists and MEPS in the European Parliament. The initiative sought to identify the best ways to encourage affordable paediatric medicines and how best to include measures in pharmaceutical law.

<sup>6</sup> Use of medicinal products in children which are not specifically approved for paediatric use

<sup>7</sup> "A Federal Drug Administration survey found that 6 of the 10 products used most frequently off-label or on an unlicensed basis in the US were off-patent". Commission consultation on a draft proposal for a European Parliament and Council Regulation (EC) on medicinal products for paediatric use. 8 March 2004 p 5.