EUCOPE

European Confederation of Pharmaceutical Entrepreneurs AISBL

THE PAEDIATRIC REGULATION: OUR PROPOSALS IN BRIEF

The European Commission has launched an evaluation of the Orphan Medicinal Product (OMP) and Paediatric Regulations. EUCOPE seizes the opportunity to outline ways to strengthen the EU environment for the development of rare and paediatric disease treatments, of which the Regulation (EC) No 1901/2006 on medicinal products for paediatric use (Paediatric Regulation) is a key pillar.

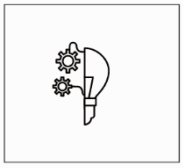
OUR APPROACH AND COMMITMENT

The review of the Paediatric Regulation should recognise that addressing paediatric unmet needs in rare diseases cannot be solved at the EU level alone. EUCOPE looks at solutions along the ***whole lifecycle of paediatric therapies*** through ***multi-stakeholder collaboration***, involving Member States, medical and research community, biopharmaceutical industry and patients. EUCOPE's membership consists of European and global companies committed to Europe and to ensure that ***Europe remains an attractive location to undertake research and launch products for children and rare disease patients*.**

OUR PROPOSALS

We call upon the Commission, the Parliament and the Council of the EU to**:**

1. **Support an environment that actively stimulates Paediatric R&D**: Building on existing platforms, including EU funded paediatric R&D projects and pulling together the scattered and scarce resources in the paediatric field will help to further R&D for medicines for children in Europe. We support a full implementation of the 2018 Paediatric Action Plan. We call upon the Commission to consider different ways to improve PIPs in the current legal framework. To ensure a predictable, yet sufficiently flexible, regulatory framework, the ***PIP should be a high-level plan***, with only ***some basic elements agreed upfront*.**



2. **Create a broad paediatric disease unmet need framework that attracts developers to underserved areas**: Paediatric unmet needs differ from rare disease patients' unmet needs and there are additional differences across the spectrum of paediatric needs as well e.g., infants, toddlers and adolescents. Rather than defining unmet need in the Paediatric Regulation, we call for a broad, ***criteria-based approach*** to medicine designation.

3. **A predictable and attractive incentive system aimed at fostering paediatric medicines development:** While the current incentive system has significantly contributed to fostering the development of paediatric therapies, the revision provides an opportunity to enhance the predictability and attractiveness of the incentive's framework for children's medicines.
   - ***Strengthening and expanding the resources of the current PRIME*** scheme to support further paediatric and rare disease innovation;
   - ***Maintaining Supplementary Protection Certificates (SPC) as primary incentive*** complemented (and not replaced) by additional incentives;
   - Taking into account that small to mid-sized companies would be less able to benefit from or would be ***disproportionally penalised by a system where incentives are linked to access***.

Read the EUCOPE Paediatric Regulation Position Paper: here