efpia

European Federation of Pharmaceutical Industries and Associations

Off-Patent Medicines Developed for Children

Point of View of EFPIA

View Point On Regulation

- Welcome Regulation aimed at addressing the problems resulting from the absence of suitably adapted medicinal products for the paediatric population in particular
  - inadequate dosage information
  - non-availability to the paediatric population of therapeutic advances
  - « suitable formulations and routes of administration as well as use of magistral or officinal formulations to treat the paediatric population which may be of poor quality »

View point on rewards and incentives

- **Medicinal Products covered by IP rights: obligation to submit paediatric data in compliance with an agreed PIP (unless waiver) and possibility of a reward under certain conditions – Obligation systematic; how often will all conditions for obtaining a rewards be met?**
- **Medicinal Products not covered by IP rights: possibility to submit paediatric data in accordance with an agreed PIP with a view to obtaining a Paediatric Use Marketing Authorisation - such an initiative is to be rewarded by 8+2 data and marketing protection periods for this Marketing Authorisation.**

View point on PUMA

- Positive aspects:
  - Aims at encouraging companies to seek authorisation and if necessary conduct appropriate studies in medicines used to treat (or considered potentially useful to treat) the paediatric population.
  - Aims at encouraging the development of suitable formulations and/or routes of administration

View point on PUMA

- Positive aspects
  - Possibility to benefit from free Scientific Advice
  - Obligation to market in all MS: less stringent than for obtaining 6-month extension of IP protection (for patented products)
  - Possibility to rely on bibliographic/ existing data to a large extent

View point on PUMA

- Uncertainty
  - Paediatric use authorisation will be granted to a specific medicinal product based on data supporting appropriate risk benefit balance in paediatric indication concerned at defined dosage regimen using suitable formulation and route of administration. What will prevent use of other medicinal products containing the same substance in the same paediatric indication/population (e.g. what will prevent use of magistral or officinal formulations?) – At this time no pan European mechanism developed to prevent this.

View point on PUMA

- Uncertainty (cont'd)
  - What will prevent use of the statement « active substance which is contained in (XX) is also authorised to treat other conditions which are not mentioned in this leaflet. Ask you doctor or pharmacist if you have further questions »?