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The role of the Paediatric Initiative

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Worldwide there is a recognised lack of medicines approved for the paediatric population. The implication is that children currently are prescribed medicines developed and approved only for adults, at dosages that are empirically determined and with formulations not appropriate for their specific age subset. Estimates from Europe suggest that about two thirds of medicinal products prescribed for children have not been adequately studied for paediatric use.

The differences between children and adults in relation to medicinal products are well known by pharmaceutical companies and physicians who should respectively develop and prescribe them. Children differ in the way they ingest, absorb, metabolize and excrete drugs, and behavioural and developmental issues influence their treatment. These factors are not constant but change and evolve as the child grows. Accordingly "the paediatric population" has been stratified in a number of subsets, including preterm infants, newborn infants (0–27 days) infants and toddlers (28 days to 23 months), children (2–11 years) and adolescents (12 to 16–18 years, defined differently in different regions). Age-related differences mean that many medications have different therapeutic effects and adverse reactions in children compared with those in adults.

Doses for adults tend to be fairly uniform, without large differences between individuals, meaning that usually a limited number of formulations and strengths of a medicine is sufficient to provide the appropriate adult dose. Children, however, can vary greatly in their tolerability of dosage levels and formulations. Consequently, the need to develop novel study designs, including validation of age-appropriate outcome measures to reflect these differences, adds complexity and creates practical issues specific to paediatric research.

There is an increasing effort in addressing these challenges, highlighted in particular by the recent legislative changes in Europe, with the release of Regulation (EC) No 1901/2006 which constitute the most recent legislative setting expected to address the hurdles.

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