**Expanding therapeutic options for neonates and children**

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Access to appropriate and effective medicines for neonates and children continues to lag behind that for adults. This disparity is largely due to several challenges, including a relatively small pediatric market, limited availability of child-friendly formulations, and the inherent complexities of conducting clinical trials in neonates and young children. Although regulatory initiatives such as the Pediatric Study Plan (PSP) mandated by the U.S. Food and Drug Administration (FDA) and the Pediatric Investigation Plan (PIP) required by the European Medicines Agency (EMA) have led to greater inclusion of children in the drug development process, a substantial number of medicines, particularly those considered "older" or off-patent, continue to be used off-label in pediatric care. This is especially problematic in neonates, where evidence-based dosing recommendations remain scarce. The dynamic physiology of neonates and infants further complicates drug development. Organ immaturity, varying enzyme expression, and developmental changes in drug absorption, distribution, metabolism, and excretion (ADME) significantly alter pharmacokinetic and pharmacodynamic profiles. For example, a neonate's body weight doubles by 6 months and triples by 1 year, underscoring the need for precision dosing that accounts for these developmental changes. To address these challenges, global pediatric clinical trial networks have been established to coordinate research efforts, pool resources, and standardize methodologies. These networks enable multinational, multisite studies focused on improving the safety and efficacy of therapeutics in children. In parallel, strategic initiatives such as the World Health Organization’s Global Accelerator for Paediatric Formulations (GAP-f) and the Medicines Patent Pool are helping to accelerate formulation development, ensure equitable access, and promote uptake of essential pediatric medicines in low- and middle-income countries. Continued innovation and international cooperation are essential to expand therapeutic options and improve health outcomes for neonates and children.