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Pediatric Formulations: Healthy Tomorrows For Children

Article Courtesy of Piramal Pharma Solutions Inc.

Formulations developed specifically for children with safe and effective pharmacotherapy requires the timely development of medicines and information on their proper use that suit the age, physiological condition and body sizes of the child. Common routes of administration in pediatric patients include oral (especially liquids), parenteral, dermal, pulmonary, nasal, rectal and ocular uses.

Lucrative Market for Pediatric Formulations

Pharmaceutical companies witness the saying "Children are the future of the nation." Long ignored, the pediatric population — which makes up 20 to 25 percent of global population — is beginning to emerge as an opportunity area for pharmaceutical companies. The global market for pediatric medications was estimated at $83.6 billion in 2014, rising by about 4 percent annually to 2019 when it will reach $100.7 billion.

Pharmaceutical companies leverage the "Pediatric" formulation exclusivity as part of late life cycle management. Every dollar spent for pediatric formulation reaps much more benefit than any other extension strategy. Vaccines, inflammatory diseases, respiratory conditions and viral infections are key therapy areas, in addition to central nervous system (CNS) treatments and oncology.

The growth of specialty drugs under the Orphan Drug Act has been a boon for pediatric medicine, as many of the orphan diseases being targeted today express themselves in children. In addition, legislative action in this century, notably the Best Practices for Children Act (BPCA) and Pediatric Research Equity Act (PREA) provide a carrot-and-stick approach to focusing

pharma on childhood disease. PREA, in particular, provides a checkpoint for every drug seeking FDA approval.

Over the same time period, 563 pediatric label changes have been made in response to BPCA and PREA — an average of 37 label changes per year.

Challenges in Developing Pediatric Formulations

1. Diversity of Children
- Size/weight increases 20-fold from birth to adulthood.
- Dose adjustments of fourfold or greater often needed.
- Ability to take medicines and dosage form preferences vary greatly with age

2. Taste Masking
- Taste perception/preferences are different in children than adults; disease state can also impact taste/smell perception.

3. Stability
- Chemical, physical, microbial.
- Oral liquids present additional stability challenges due to additional excipients needed for palatability.
- Expiration period may be too short to support commercial feasibility.

4. Low acceptability and palatability in children.
5. Concerns over off-label and unlicensed use of medicines in children.
6. Achieving global regulatory acceptability.
7. Providing rapid patient access (limitation of diseased children population for clinical trials) and accelerated development timelines.
8. Risk management of compounding and manipulation of medicines for children.

Piramal Capabilities (Booth #1703)

Piramal Pharma Solutions has scientific capability and expertise in pharmaceutical development, meeting the age-appropriate and regulatory requirements of the following pediatric formulations:
- Oral liquids (solutions/suspensions).
- Chewable tablets.
- Mouth dissolving (dispersible) tablets.
- Powder for reconstitution.

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PIRAMAL PHARMA SOLUTIONS

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- Effervescent powders/tablets.
- Parenterals.
- Age appropriate tablets and capsules.
- Design regulatory strategy, clinical applications, review of CMC and clinical study reports.

Taste Masking Technologies

In addition to simplistic approaches for pediatric formulations, Piramal R&D development services can offer Taste Masking technologies to achieve desirable formulations.