Journal of Ayurveda & Holistic Medicine

https://jahm.co.in eISSN-2321-1563

Editorial

PAEDIATRIC DRUG REGULATION IN AYURVEDA: CURRENT GAPS AND STRATEGIC SOLUTIONS

GIRISH K J Editor-in-Chief

REENA KULKARNI Senior Editor

Access This Article Online:	Website Link:	CITE THIS ARTICLE AS
Quick Response Code:	https://jahm.co.in	Girish K J, Reena Kulkarni. Paediatric drug regulation in Ayurveda: Current gaps and strategic solutions. *J of Ayurveda and Hol Med (JAHM).* 2025;13(5):1-3.
	DOI Link:	
	https://doi.org/10.70066/jahm.v13i5.1992	
	Corresponding Author Email:	
	drreenakulkarni@sdmayurbangalore.in	

Children are assets of nation and future of the country. They are a set of vulnerable groups with regards to health concerns, clinical applications of medicines and research as well. Crucial efforts are already set in towards developing standard guidelines to frame treatment protocols, drug choices and therapies that are essential for safe and effective implementation of new drugs while enhancing the safety of already in vogue standard prescriptions. Drug dosages and usage of drug forms based on extrapolated data from research on adults have led to under dosages, lesser effectiveness and adverse events at times. At a global level while the efforts are on to bring together the regulatory authorities and pharma industry to finalize the guidelines for the clinical investigations of medicinal products in paediatric population. Many of the countries through their respective regulatory bodies have already implemented legal landscapes required mandatorily for development new products and optional for known medicinal products intended to be used in Paediatric population. Chinese medicine goes a step ahead by framing guidelines for the use traditional Chinese medicines and exceedingly working on generating evidence through clinical research. In fact, there have been impactful changes and advancements seen in pediatric drug regulation, labeling, dosage and research after the introduction of Best Pharmaceuticals for Children Act (BPCA), Pediatric Research Equity Act (PREA) in 2012 by FDA in United States. However, despite these massive efforts there is a slow drifting paradigm towards Ayurveda for herbal and natural therapies to children owing to drug resistance, unsolved mystery behind recurrent illnesses despite overly use of vaccines and lack of other preventive interventions. [1-2]

Ayurveda, the Indian traditional system of medicine uniquely suited to Indian tropic caters treatment options for all the age groups in various specialty branches. *Kaumarabhritya –Bala roga* is the specialty branch dealing with child health care and management of Pediatric illnesses. Various physical, physiological, psychological and immunological immaturities in this

age group earns them a category of *sukumara* (tender, vulnerable populations) akleshasaha (intolerant to withstand the effects of *teekshna* drug or therapy). Accordingly, traditional guidelines emphasize on use specialized approach, ensuring the selection of *hridya* (mild) medicines, in an appropriate dosage, and therapies tailored to meet the child's specific needs. Interestingly, the age classification is derived to suit the nutritional and pharmacological needs of children who are in the dynamic phase of growth and development. Further, there are clear and general instructions available on selection of medicine for a child such that it should be sweet, astringent, milk based or as an adjuvant with mild potency. Strong and caustic medications are to be generally avoided unless until the health condition of the child demands for its usage. So also, *Panchakarma* therapy is to be limited to mild cleansing and external supportive therapy. Therapeutic drastic detox therapies are to be avoided unless until essential.

We conducted a survey on 200 classical Ayurveda and 100 patented drug dosage forms from various pharmaceutical companies. For our surprise almost all the classical medicinal brands that we surveyed had mentioned date of manufacture, date of expiry, dosage instructions. Similarly majority patented paediatric medicinal preparations had these instructions. However, the specific instructions pertaining to age specific dosage, best suited adjuvant, caution about sensitive ingredient like *kshara* (alkali), *bhallataka* (Semecarpus anacardium Linn.) etc. and their restraint usage or storage were lacking. Similarly, a possible drug interaction with co-administered medicines, probable adverse reactions needs further up-gradation. These can be true in real sense only when effective researches are done in paediatric population. This should follow certain amendments with regards to existing guidelines, legal permissions, financial benefits and most importantly robust encouragement from the government.

Central council for research in *Ayurvedic* Sciences (CCRAS) under Ministry of AYUSH, Government of India is the governing body for research and drug regulations in Ayurveda. CCRAS has already published general guidelines for drug development of Ayurvedic formulations in 2018. [3] However, specific guidelines for paediatrics are still a grey area in this first draft. Further, there are ample opportunities to research on new drug development, establish pharmacokinetics; pharmacodynamics and target specific action of these drugs either through direct pharmacological or reverse pharmacological approach. Recently there have been flashing improvements in network pharmacology and in silico studies exploring huge potential in Ayurveda drug research. CCRAS in association with CSIR, Central Drug Research Institute (CDRI) and other institutes have already involved in new drug development. Their labeling and other packaging instructions have been a model. But these are very limited and mostly towards non communicable disease. Recently, CCRAS have even initiated innovative funding modalities at under-graduate, post-graduate and practitioner level through SPARK, PG STAR and SMART streams. Additionally, Ayush Suraksha is one of the important pharmaco-vigilance programmes in India for monitoring the drug

safety of medications, specific materials, and procedure-based therapies in Ayurveda, Siddha, Unani, and homoeopathy (ASU&H) medicines. Dr. Bhushan Patwardhan [4] in his editorial opines that there is a deficiency in data generated from the community usage of these discoveries and relevant scientific publications in indexed journals. There is a need of quick attention and surveillance from the governing bodies to establish research mind set in Ayurveda practitioners especially in the field of paediatrics. Subramanian DK, Balakrishnan G [5] in their work on Pharmacovigilance Consideration for Ayurvedic Medicines in Pediatric Practice state that current guidelines fail to focus on food safety and address complex issues involved in healthy and useful microbial component in certain Ayurveda preparations not merely looking as microbial contamination. Ayurveda being individualized therapy, every instance needs to be based on tenfold specific examination prescribed for disease in question as well as diseased person. There is a mammoth responsibility on Ayurveda practitioners and herbal pharma industries to preserve and carry forward the legacy of this traditional system. Traditional child care knowledge and preventive strategy like *swarnaprashana* (gold containing electuary), *prakara yoga* (specific drugs administered periodically in childhood to prevent illness), dietary guidelines for infants and children needs a scientific innovation for better acceptance. However, midst of efforts the Ayurveda credibility should not be compromised for short term financial or personal gains. In the available guidelines while the efforts are towards establishing rules and regulations at par with the global standards to enhance world-wide acceptance. There should be strong emphasis on foundational concepts of Ayurveda based on its own principles to establish the efficacy of the drug.

References:

1. Lehmann B. Reflections on the regulatory field covering the development of paediatric medicinal products: a brief overview of current status and challenges. Frontiers in Pharmacology. 2024 Jun 3;15:1375988. https://doi.org/10.3389/fphar.2024.1375988
2. Penkov D, Tomasi P, Eichler I, Murphy D, Yao LP, Temeck J. Pediatric medicine development: an overview and comparison of regulatory processes in the European Union and United States. Therapeutic innovation & regulatory science. 2017 May;51(3):360-71. https://doi.org/10.1177/2168479017696265
3. Central Council for Research in Ayurvedic Sciences. General guidelines for drug development of Ayurvedic formulations. Vol. 1. 1st ed. New Delhi: CCRAS; 2018. Available from: https://ccras.nic.in/wp-content/uploads/2024/07/CCRAS_Guideline-of-Drug-Development.pdf
4. Patwardhan B. Ayurvedic drugs in case: claims, evidence, regulations and ethics. Journal of Ayurveda and Integrative Medicine. 2016 Sep 16;7(3):135. https://doi.org/10.1016/j.jaim.2016.08.005
5. Subramanian DK, Balakrishnan G. Pharmacovigilance Consideration for Ayurvedic Medicines in Pediatric Practice: Developing Protocols for Documenting Clinical Safety. Journal of Pharmacology and Pharmacotherapeutics. 2024 Dec;15(4):442-8. http://dx.doi.org/10.1177/0976500X241276311