

Accelerating Safer Administration of Medicines to Children in Low Resource Settings

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Bridging Stakeholder Viewpoints

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Background

Dosage in children

- Generally based on body-weight or specific age ranges
- Standardised by **weight** or **body surface area**.
- Small volumes to be administered
- Tenfold dosing errors in children can easily occur due to a misplaced decimal point or a trailing zero
- Children under the age of 2 years and paediatric intensive care unit patients are at highest risk



Administration devices for oral and respiratory medicines

Oral liquids

- Acceptable for the whole paediatric age range
- Flexible dosing



Respiratory medicines

- Local treatment of respiratory disease
- Systemic treatment due to avoidance of first-pass metabolism

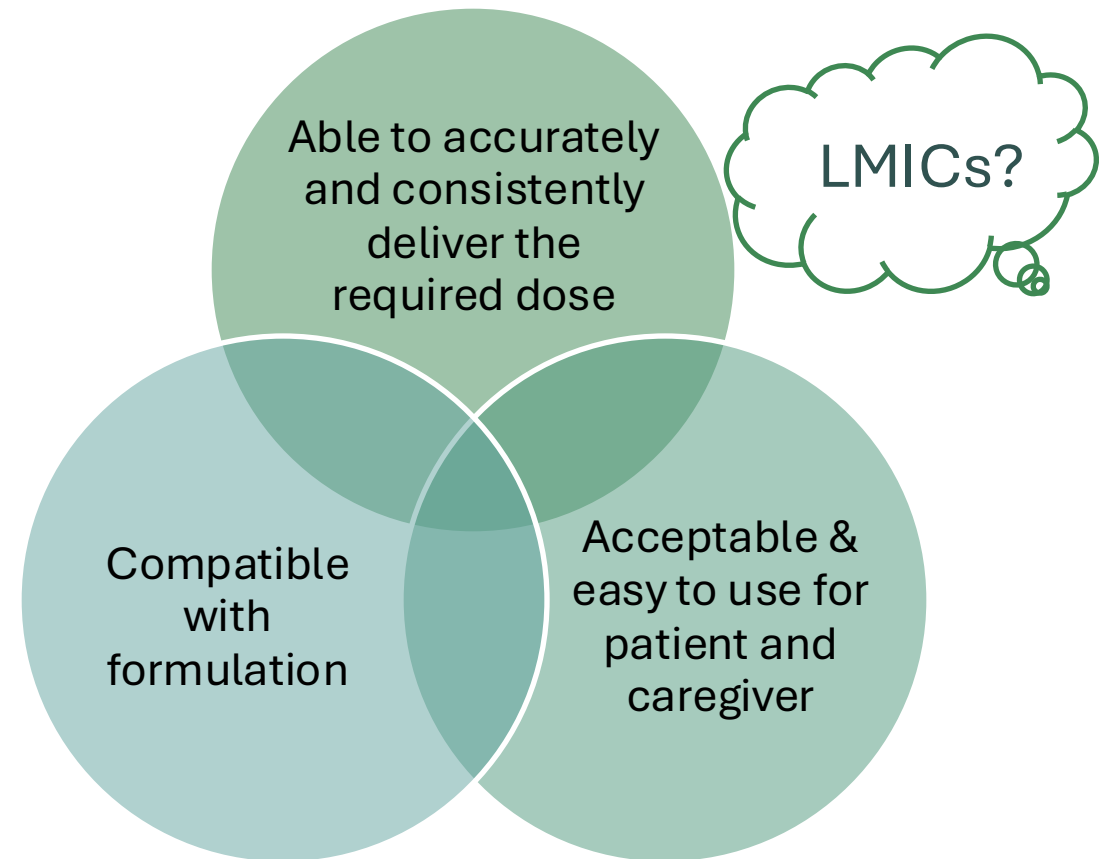


The correct dose administered via the right route → optimal clinical outcomes

Dosing & administration devices

Dosing errors may occur if

- Failure to select and use a suitable device, e.g., use of household spoon for oral liquid, use of large syringe for measurement of small dose volume
- Limited caregiver understanding of dosing instructions and/or insufficient device use directions



A stakeholder workshop on Administration Devices for Oral and Respiratory Medicines for Children in Low Resource Settings was held on March 4, 2024, at SciTech Centre, Mumbai, India.



Purpose of the workshop:

- To understand the acceptance of the already existing administration devices in low- and middle-income countries
- To assess the level of awareness of concerns associated with the use of administration devices as well as the need for innovative devices

Read more about the workshop on UCL News:

<https://www.ucl.ac.uk/pharmacy/news/2024/may/accelerating-safer-administration-medicines-children-low-resource-settings>

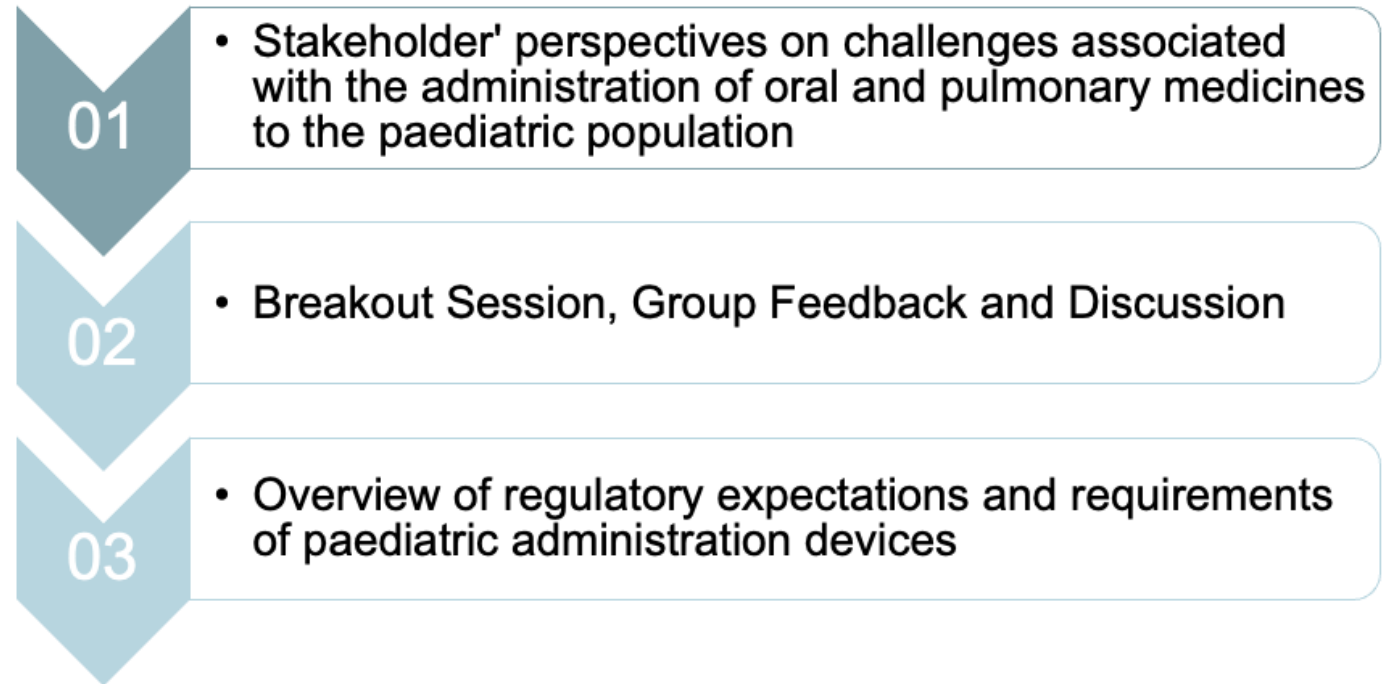
Method



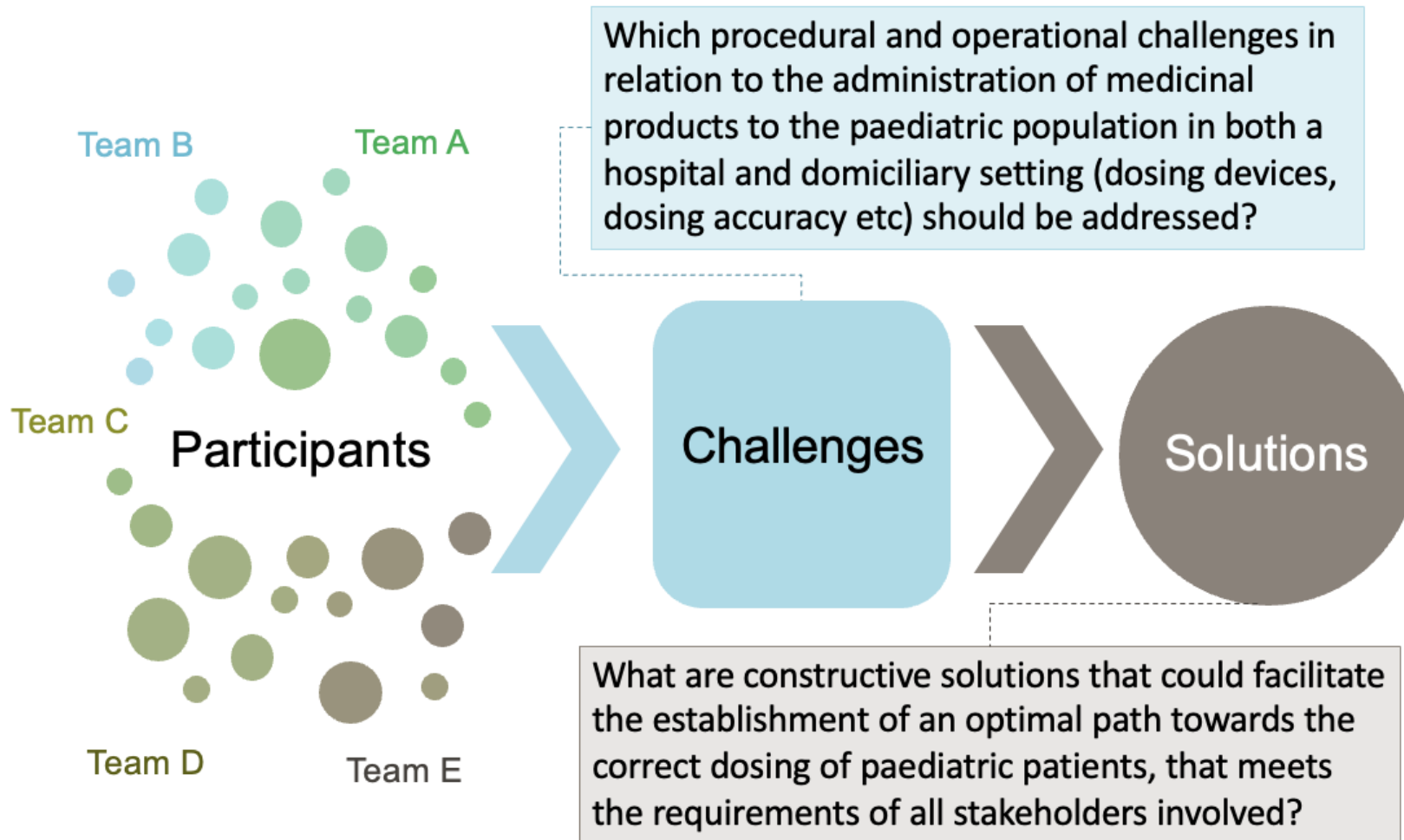
The workshop was organised in partnership with:

- The Indian Pharmaceutical Association (IPA)
- European Paediatric Formulation Initiative (EuPFI)
- The Society of Paediatric Medicines and Healthcare Initiative (PMHI)
- Thetabeta Analgorithm Pvt Ltd (TBA)

Workshop Agenda



Group feedback & discussion



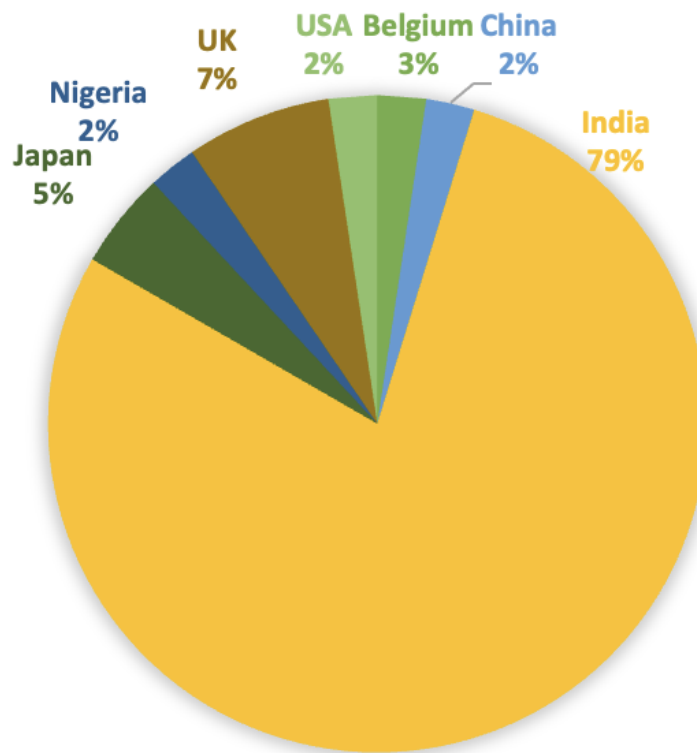
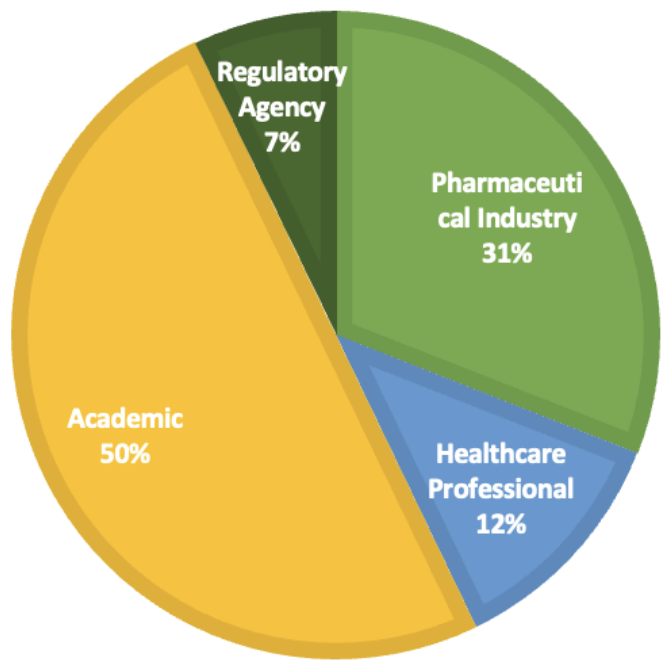
Voting was then used to ascertain the participants' preferences for the proposed solutions.



Results

Participants

- Pharmaceutical Industry
- Healthcare Professional
- Academic
- Regulatory Agency



Usability of administration devices - global landscape

	Europe + USA + Israel	India	China	Japan
Data collection timescale	Nov 2020 - Jul 2021	Nov 2020 - May 2021	Sep 2022 - Oct 2022	May 2021 - Aug 2021
Participants numbers	206 adults and 43 children	574 adults and 120 children	749 adults and 215 children	364 adults and 70 children
Medicine used	65% oral, 12% inhaled, 23% both	71.5% oral, 6.3% inhaled, 22.2% both	51.1% oral, 11.1% inhaled, 31.5% both	oral only
Oral medicines	Liquids (58%) : syrup > suspension > drops. Solid (40%): tablets > capsules > granules	Liquid (66%): syrup > suspension > drops Solid (34%): tablets > capsules > granules	Granules > syrup > tablet > suspension > capsules > drops	Powders/granules > liquid (in young) > solid tablets
Oral administration devices	Oral syringe > measuring spoon > household spoon > measuring cup > dropper	Measuring cup > household spoon > dropper > measuring spoon > oral syringe	Measuring cups > household spoons > measuring spoon > dropper > oral syringe (others: bottle cups, bowls, water cups)	Household spoon = dropper > measuring cup > oral syringe
Ease of use (oral)	Easy to use	Easy to use	Easy to use	Easy to use
Instructions (oral)	50% of adults and children received instructions. 50% of adults received by healthcare professional, 44% by PIL/label. 60% of children received by parents.	73% received instructions. 60% of participants received by healthcare professionals.	> 70% received instructions. Children usually do not receive instruction.	53% received some instructions.
Clarity of instruction (oral)	Clear	Clear	Clear	Clear
Respiratory devices	pMDI with/without spacer > nebulisers with/without facemask > mist inhalers > drypowder inhalers	Nebulisers with facemask > manually-actuated MDI > breath-actuated MDI > dry powder inhalers > mist inhalers > spacers	Nebuliser with facemask > spacer > dry powder inhaler > breath-actuated MDI	NA
Ease of use (respiratory)	Easy to use	Easy to use	Some easy, others difficult (i.e. mist inhaler)	NA
Instructions (respiratory)	Provided by healthcare professionals, to children provided by parents too	Provided by healthcare professionals	Provided by healthcare professionals	NA
Clarity of instruction (respiratory)	Clear	Clear	Clear	NA

Indian HCP perspectives

Common paediatric formulations

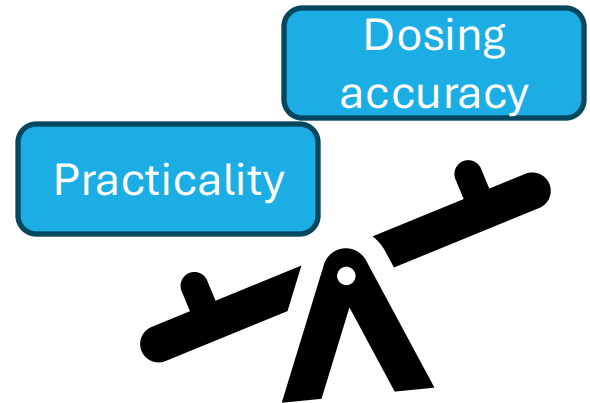
- Liquid syrups
- Tablets
- Pastilles
- Injectables
- Capsules

Frequently used oral administration devices

- Droppers
- Measuring cups
- Household spoons
- Syringes
- *Paladai

Respiratory devices

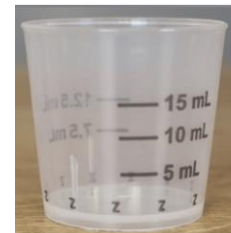
- Nebulizers most frequently used
- Mask-interface compatibility issues due to limited mask size and shape.



Common Indian household practice



Measure



Feed



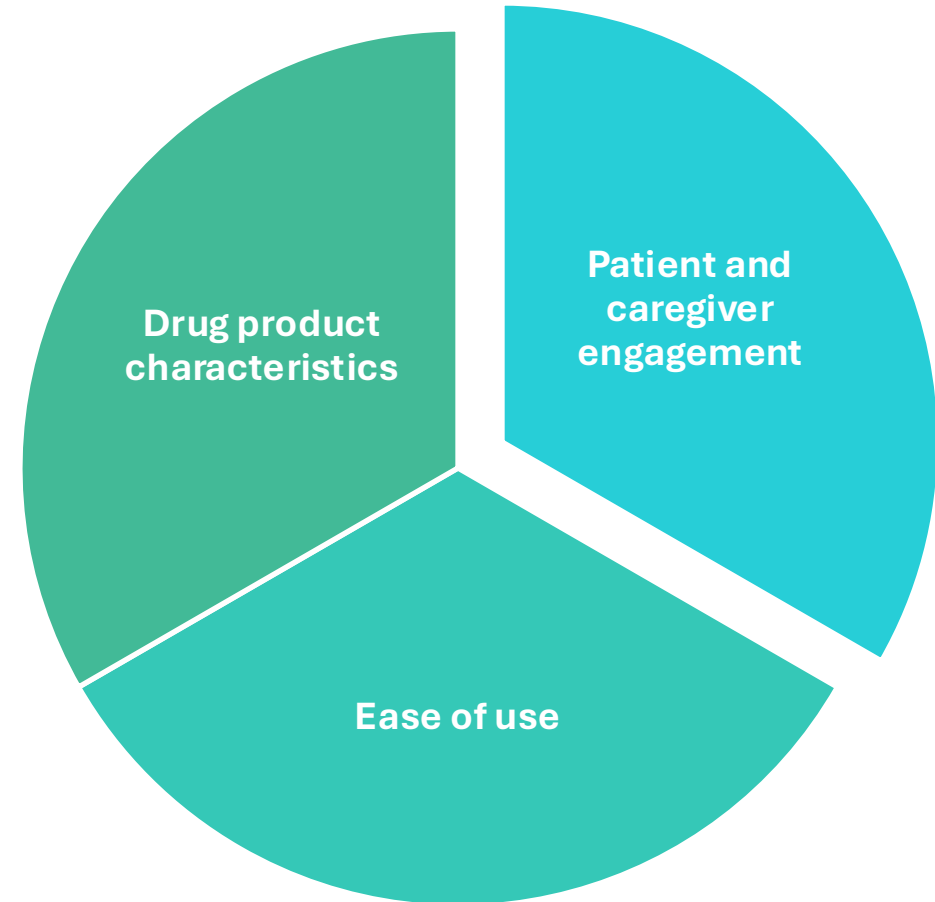
Industry perspectives – product development

In Europe

- Patient-centred approach
- Design validation through user feedback
- Heightened regulatory requirements surrounding dose accuracy, dose markings and product labelling.

For example:

- European Medical Device regulation (EU 2017/745)
- Usability requirements (ISO 62366), quality management (ISO 13485), and risk management (ISO 14971)



Industry perspectives – product development

In India

- Innovation of paediatric medical products takes into consideration the problems encountered by the children and parents when a medication is given to children.
- Prioritize the need to simplify the dosing and feeding process.

Example products & innovations by Aptar Pharma (India)



Oral drops metered dispenser



Bag-On-Valve™



SimpliSqueeze™



Regulatory perspectives

UK:

Guideline on pharmaceutical development of medicines for paediatric use (EMA/CHMP/QWP/805880/2012 Rev.2)

- Measuring device often has to be the administration device
- Small doses: suitably accurate, age-appropriate
- Variable doses: suitable to measure all recommended doses

Encourages the licensing of medicines that are supplied with devices meeting these requirements, accompanied by suitable instructions for use.



India:

Drugs and Cosmetics Act 1940; The Medical Devices rules 2017

- Medical devices which do not have a predicate device need to undergo through a clinical investigation to establish safety

Ambition to expand into innovative drug development and global market

The industry and public sector organizations to support advances in paediatric healthcare, specifically medical devices developed to accommodate the pharmacotherapy needs of paediatric population



Regulatory and funding bodies need to keep pace with the rapidly expanding field, ensuring a patient-centric approach that safeguards younger patients.

Challenges identified during team discussion

Challenges associated with administration of oral medicines

- Accuracy in dosing small volumes
- Spillage
- Loss during transfer
- Cleaning
- Mishandling
- Fear induced by syringe shapes
- Imprecise graduation interval
- Hold up volume in dispenser

Challenges associated with administration of respiratory medicines

- Restriction in mask size
- Acceptance is less in children
- Longer administration time
- Stigma that such devices should only be used for serious illness

Voting results for potential solutions

Proposed Solutions	Number of Stakeholder Votes for each Solution		
	Industry	Academic	Regulatory
Awareness raising and education <ul style="list-style-type: none"> • Patient counselling • Dissemination • Instructions in different languages • QR code video instructions 		●●● ●●●	
Device Innovation <ul style="list-style-type: none"> • Customisation of existing devices • AI assisted / Digital device • Patient engagement / End user perspective during development 	●●●	●●● ●●	●●
Regulations <ul style="list-style-type: none"> • Regulations harmonisation • Regulations on material of device / packaging 	●●●	●●●	●●

Conclusions

- Inadequate public awareness about paediatric medication safety, low end-user involvement during product design, and the lack of regulation harmonisation posed significant challenges to the development and implementation of innovative devices for safer medication administration to children in India.
- It was advocated that all stakeholders involved must take urgent actions and address these challenges collaboratively.
- Discussions and knowledge shared during this event showed the effectiveness of the workshop in fostering a deeper understanding of the issues regarding development, control, and supply of administration devices in low resource settings.
- It is evident that organising more such events in the future will be instrumental in further enhancing public awareness, driving policy changes, and ultimately ensuring well-being of children

Thank You!

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- Speakers



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