



European Federation of Pharmaceutical
Industries and Associations

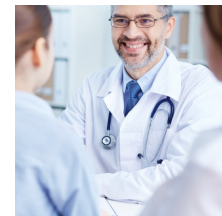


Paediatric Formulations

Dr Alastair Coupe, 23rd May 2018



**“Unlocking
Tomorrow’s Cures”**



Why do we need specific FORMULATIONS for children?

Kids aren't just little adults.

**Drugs approved
for adults may
not fit kids'
needs.**



Why do we need specific FORMULATIONS for children? ...children are our future!

To ensure drugs are developed and studied for use in children (“unmet medical need”)

- * Aiming to reduce “off-label” use of adult formulations due to the lack of oral paediatric specific dosage forms

To align with regulatory requirements

- * The **Paediatric Regulation** came into force in the EU on 26 January 2007
- * **Five year report** of the Regulation (2013) concluded that paediatric development has become a more integral part of the overall development of medicinal products in the EU
- * **Ten year report** (2017) stated that the Regulation has had considerable impact on the development of medicines and paediatrics is an integral part of the overall development of medicines in the EU.

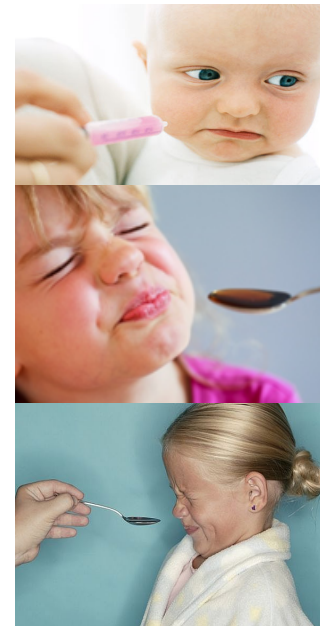
To ensure the safety and efficacy of drugs in the paediatric population

- * Children are growing and developing and must not be viewed simply as little adults
 - * Challenges include ability to swallow “large” dosage forms e.g tablets developed for adults
 - * Liquid dosage forms often have unacceptable tastes (highly bitter)
- * Children and adults may react differently
 - * Excipients may not have been tested in children and may lead to adverse events
 - * Low tolerance to taste leads to poor compliance /adherence
- * Dosing requirements for children may be different
 - * Doses typically need to be flexible for size / age of child
 - * Many current paediatric products require manipulation e.g cutting /crushing of tablets and dispersing in food

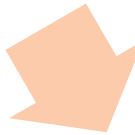
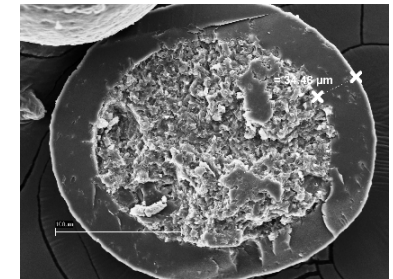
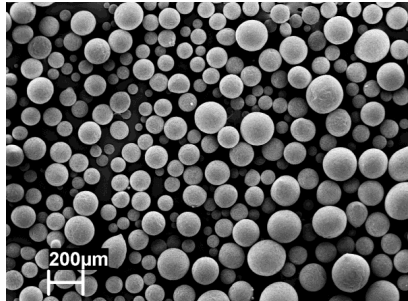
Age-appropriate dosage forms must be considered and developed as needed



Better medicines for children



New Paediatric Platform Technology: Additional Capabilities Beyond Oral Solutions...aversive taste!



Press Release of the winners from the “open innovation” challenge announced Dec 15, 2016

Pediatric Open Innovation Challenge Grantees Awarded \$50,000 by the Institute for Pediatric Innovation

The Institute for Pediatric Innovation (IPI) and [Pfizer](#) have partnered to award two \$50,000 grants to medical companies for the development of a device to dispense potentially life-saving medicines for children in low-resource settings. Pfizer has developed a new formulation for pediatric drug administration, and together with IPI held a challenge for companies from around the country to design a dispensing device for pediatric drug formulation.

Twenty-five applicants submitted designs for the challenge

Two different devices were chosen as winners:

- * **HS Design and Rochling**
- * **Balda**

Seed Grants were awarded of \$50,000 to each winner
(the winning entity retains ownership of related intellectual property)

Two year timeline, working with IPI, to advance the dosing devices

Microsphere/Multiparticulate Dispensing Device



Child Friendly Delivery System

- Spill-proof
- Direct delivery to child's mouth
- Chew resistant outer shell
- Clog resistant

Versatile Bulk Container

- On site fill capability
- Engineered to be humidity resistant
- Customizable for your volume and branding needs
- Compatible with child-proof caps

Novel Interlocking Design

- Simple to use
- Prevents accidental drug spills
- Automatically seals against contaminants

User Friendly Dose Settings

- Multiple dose settings in a single platform
- Customizable by pharmacist or caregiver to meet the needs of the patient population

Intuitive Dispensing Platform

- Dispenses similarly to liquid oral syringe
- One handed operation
- Reusable and easy to clean

Syringe Size	Dose Increments (mL /g)	Min. Dose (mL /g)	Max. Dose (mL /g)
1 mL	0.125 / 0.082	0.54 / 0.35	1.062 / 0.690
2 mL	0.230 / 0.149	0.172 / 0.112	2.242 / 1.457

Formulation design for children

Innovation through “external crowd sourcing” and “open innovation”



✗ A lot of medicines
taste bad



✓ We developed
tasted masked
beads technology



✓ Easy to use, kid
friendly and flexible
dosing solution

2015

2016

2017

2018

“If you want to go quickly, go alone.
If you want to go far, go together.”

Thank You and Questions



“Drugs don’t work in patients who don’t take them.”

C. Everett Koop, MD US Paediatric Surgeon / Surgeon General