

The Goodman Pediatric Formulations Centre (GPFC)



BIO-EUROPE®

Why are we here?

- In Canada, we do not have access to the appropriate commercial formulations
- This can cause therapeutic ineffectiveness, adverse events or even treatment failure



True Cases

- 8-month-old liver transplant recipient with organ rejection
- 18-month old asthmatic infant refusing to take his prednisone
- Parents of a 3-year-old child with leukemia make a cytotoxic medicine at home
- 9-year-old boy died from a baclofen overdose thinking he was taking tryptophan, for his sleep disorder



Children are Not Mini Adults



- Metabolize drugs differently
- Developmental stages may mean variable drug responses
- Efficacy and safety may not be known or studied
- Administration is based on age group



One Size Does Not Fit All

Adult formulations may not serve children well:

- Taste acceptance/compliance
- Route of administration and dose flexibility
- Dosing concentration and volumes
- Drug excipients (e.g. alcohol or sugars)
- Ease of dosing
- Stability and bioavailability



The Result is the Practice of Compounding to Adapt Adult Forms

- Many pediatric formulations exist in the United States and Europe but are not commercialized in Canada

Resulting in....

- Off-label use to adapt the adult form to an appropriate child-friendly form
- Compounding of the medication at the pharmacy

As many as 75% of all pediatric prescriptions may fall outside regulatory approval in Canada.



Why do These Formulations Not Exist in Canada?

- Mid to small market size
- Regulatory and reimbursement path (perceived to be) unclear
- Reimbursement landscape is complex and cumbersome
- No incentive for investment
- Many drugs are off-patent



The GPFC is advocating in these areas to make change and to facilitate bringing these medicines to Canadian children.



Partnerships with Industry to Facilitate Access in Canada

- The GPFC has a priority list of medicines
- Seeking partners to facilitate bringing already existing commercialized formulations to Canada



We have facilitated the regulatory submission of two drugs on our list with NOCs expecting in 2019.



Partnering to Develop Innovative New Pediatric Formulations

- Our priority list includes highly needed pediatric formulations that do not exist anywhere in the world
- Our aspiration is to innovate to develop appropriate formulations for child-friendly administration with dosing flexibility
- We are looking at two new innovative pediatric formulations

Currently in discussions with one partner to develop a new pediatric formulation for global commercialization.



Opportunity to Partner with the GPFC for Post Approval Commercialization

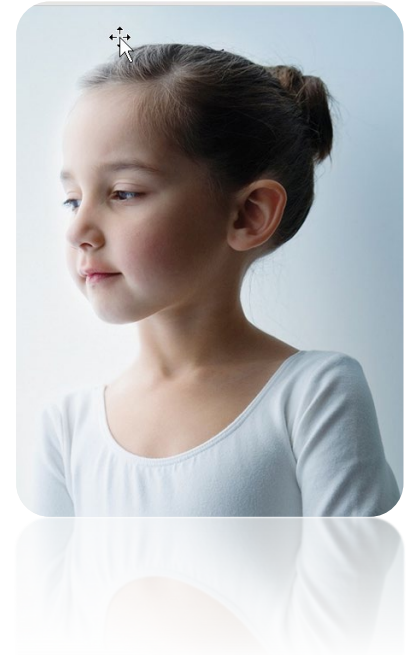
Once we have submitted to Health Canada ourselves, we will need a commercial partner or investor to market the product.



Let's collaborate for improved access to pediatric formulations.....

Our value added to the Canadian market is:

- Network of HCPs
- Knowledge about pediatric formulation regulation in Canada
- Ability to openly discuss approach with stakeholders
- Advocacy to increase access to pediatric medicines



We Leave you with a Video that Provides the Challenges from a Parental Point of View



<https://youtu.be/4kDxlhabb7I>



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