National Priority List of Pediatric Drugs: Nomination Submission Form

National Priority List of Pediatric Drugs

In 2020, Health Canada launched the Pediatric Drug Action Plan (PDAP), with the ultimate vision that children in Canada have access to safe and effective medicines in age-appropriate formulations. As part of this work, Health Canada is seeking input from the pediatric medical community (including pediatricians, pediatric subspecialists, family physicians and pharmacists) to establish the first National Priority List of Pediatric Drugs (NPLPD). The list will address areas of unmet medical need in Canada's pediatric population.

Why create a National Priority List of Pediatric Drugs?

Currently, many important medicines are not approved for sale in Canada for children. This includes drugs that are not available in any indication, as well as drugs that are prescribed to children "off-label". Off-label use is when a drug is prescribed outside of its approved use as set out in the drug's product monograph.
Some examples of off-label use include using:

- a drug for the indication on the label but not for the approved age
- a drug for another indication than the one(s) on the label
- a route of administration different than that on the label

The lack of appropriate, evidence-based labelling of pediatric drugs can lead to efficacy and/or safety issues. For example, the drug must be compounded and this can lead to dosing errors.

The NPLPD will help identify urgently needed drugs for pediatric populations that are currently not approved for sale in Canada or are only available for use off-label. The goal of the NPLPD will be to facilitate access to these drugs for children in Canada.

Nominating a drug for the National Priority List of Pediatric Drugs

Thank you for taking the time to share your expertise and contribute to this important initiative.
Your experience and knowledge are key to identifying the drugs and biologics most relevant to children. Health Canada recognizes that different medical providers have varying knowledge about the details of a drug's label and approval status. Please do not let gaps or uncertainty deter you from submitting this form. Simply complete the form to the best of your ability.

If a drug identified in a nomination form fulfills the following criteria, it will be considered for inclusion on the NPLPD:

1. Based on your experience, this drug addresses disease(s) / disease area(s) / condition(s) with high unmet need

   AND

2. To your knowledge, this drug currently lacks:
   a. Approval for sale in Canada **OR**
   b. A pediatric indication (for instance, a drug that is currently marketed in Canada with only an adult indication and/or a pediatric indication limited to certain age groups) **AND/OR**

c. A child-friendly formulation (for instance, a drug that is currently available in Canada only in a formulation designed for adults)

AND

3. This drug is approved for sale in a trusted foreign jurisdiction with an established pediatric indication and/or child-friendly formulation (this criterion will be verified by Health Canada)

Instructions:

For a drug to be considered for the NPLPD, Health Canada is asking that drugs be nominated for inclusion on the list by using this form. This is the main tool for collecting nominations. Use 1 form per drug. This nomination form will be accessible online from March 15, 2023 until May 14, 2023.

Your experience will help Health Canada and Health Canada's Pediatric External Reference Group (experts in the medical and pharmaceutical field) create a list of most needed pediatric drugs in Canada. The list is expected to be updated on a regular basis.

There is no limit to the number of drugs you are allowed to submit for consideration.

By completing this nomination form, you authorize Health Canada to make use of this information.

1.) Please identify the drug or biologic that is being nominated (for which there is an unmet pediatric need) including:

Drug or biologic (select one) **(required)**

- ○ Drug
- ○ Biologic

Name of drug (commercial and generic names) **(required)**

Route of administration [Select all that apply] **(required)**

- [ ] Oral
- [ ] Sublingual
- [ ] Nasal
- [ ] Topical
- [ ] Inhaled
- [ ] Rectal
- [ ] Intravenous
- [ ] Intramuscular
- [ ] Other

If other, please specify:

Dosage form [Select all that apply] **(required)**

- [ ] Tablet (effervescent, chewable, sublingual, enteric coated)
- [ ] Capsule
- [ ] Oral solution/Oral suspension
- [ ] Powder
- [ ] Lozenges
- [ ] Mixtures
- [ ] Implant
- [ ] Irrigation solution
- [ ] Lotion
- [ ] Gargle
- [ ] Drops

- [ ] Ointment
- [ ] Cream
- [ ] Injections
- [ ] Suppository
- [ ] Transdermal patch
- [ ] Inhaler
- [ ] Other

If other, please specify:

Strength or concentration

Therapeutic area(s) **(required)** If other, please specify:

Pediatric age range with greatest unmet need [Select all that apply] **(required)**

- [ ] Preterm newborns (less than 37 weeks)
- [ ] Term newborns (0-27 days)
- [ ] Infants and toddlers (28 days to 23 months)
- [ ] Children (2-11 years)
- [ ] Adolescents (12-17 years)

2.) Please describe the unmet therapeutic need that the nominated drug will address (for example, disease prevalence, lack of therapeutic alternatives, severity of condition) [max. 1000 characters]:

Comment box

3.) Which of the following descriptions applies to the nominated drug?

Please select all that apply. **(required)**

- [ ] The current standard of care in Canada is not as safe/effective as the proposed drug
- [ ] The drug is requested regularly through Health Canada's Special Access program
- [ ] The current gaps in labelling interfere with prescribing, adherence and/or patient's sense of safety
- [ ] The current gaps in labelling impede appropriate reimbursement and access
- [ ] The drug requires compounding at hospital/home/pharmacy to be administered
- [ ] The drug is made available by the manufacturer's compassionate use program
- [ ] There is no defined standard of care treatment for this condition/entity (for example, new molecular entity for targeted therapy)
- [ ] Unsure
- [ ] Other (Please describe, max. 1000 characters)

4.) Do you know if the drug you are nominating is approved for use in children in another jurisdiction?

Yes / No: If yes, please select all that apply. Make your selection...

- [ ] United States (Food and Drug Administration)
- [ ] European Union (European Medicines Agency)
- [ ] United Kingdom (Medicines and Healthcare Products Regulatory Agency)
- [ ] Switzerland (Swissmedic)
- [ ] Australia (Therapeutic Goods Administration)
- [ ] Singapore (Health Sciences Authority)
- [ ] Singapore (Health Sciences Authority)

☐ Other

If other (please specify):

5.) Please describe any additional information (such as relevant scientific literature) that may be important to support your nomination (max. 1000 characters).

Comment box

Annex A:

Demographic Data

What is your profession? **(required)**

☐ Pediatrician

☐ Pharmacist

☐ Family physician

Other (please specify subspecialty, if applicable):

How did you hear about the NPLPD nomination process? **(required)**

☐ Health Canada presentation

☐ Member of the Pediatric External Reference Group

☐ Colleague from the pediatric community (including social media)

Other (please specify) :

Practice setting **(required)**

☐ Hospital-based practice (academic)

☐ Hospital-based practice (non-academic)

☐ Out of hospital-based practice

☐ Other

If other (please specify):

Contact Information **(required)**

☐ Yes, I give permission for the Pediatric External Reference Group to contact me for any follow-up questions regarding this nomination:

Please specify name, affiliation, and email

☐ No, I prefer to remain anonymous

Submit

Thank you for taking the time to share your experience and expertise with Health Canada and the Pediatric External Reference Group.

The creation of the National Priority List of Pediatric Drugs relies on data collected through this nomination process. We encourage you to share this nomination form with professional colleagues in the pediatric community to ensure that the most comprehensive picture of Canada's unmet pediatric need is developed through this process. Health Canada intends to hold a public consultation, as well as a targeted industry/stakeholder consultation, on the draft NPLPD following the nomination process.