Health Canada Santé Canada

**Protected B** when completed

# Pediatric Pilot Survey

| **Drug information** |
|---|
| Drug brand name, if available: |
| Drug proper or common name: |
| Dosage form: |
| Control #, if available: |
| Dossier ID, if available: |
| Email: |

**For New Drug Submission (NDS) and Supplements to a New Drug Submission (SNDS) filings**

1. Have pediatric studies been included in this submission for any age groups between birth and up to 18 years?

   ○ No (go to question 5)

   ○ Yes. Please identify all ages (specify years or months) for which pediatric studies have been included:

2. If the submission includes pediatric studies, what is your objective for submitting these studies? (select all that apply)

   ☐ To seek a pediatric indication (includes seeking approval of new dosage forms and/or routes of administration for existing pediatric indications, which requires clinical studies)

   ☐ To increase knowledge on the use of this drug in the pediatric population through the label (excluding indication)

   ☐ To seek a pediatric data extension as per the Guidance document: Data protection under C.08.004.1 of the Food and Drug Regulations

   ☐ Other (please explain):



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3. Are pediatric studies planned or ongoing?

O No
O Yes. Please identify all ages for which pediatric studies are planned or ongoing:

4. Do you have an agreed or approved US FDA initial Pediatric Study Plan (iPSP) and/or an approved EMA Pediatric Investigation Plan (EU-PIP) that would address the pediatric age groups for which studies have not been submitted? (Select all that apply)

☐ No (go to question 6)
☐ Yes, an iPSP
☐ Yes, an EU-PIP

5. For respondents who have an agreed iPSP and/or an approved EU-PIP:

Having consulted the Guidance on submitting pediatric development plans and pediatric studies, have you provided the agreed iPSP or approved EU-PIP with this submission for participating in the pilot?

O No (go to question 7)
O Yes. To participate in the pilot, an iPSP or EU-PIP must be included with the NDS or SNDS at the time of filing. Including an iPSP or EU-PIP document constitutes participation.

6. For respondents who do not have an agreed iPSP and/or approved EU-PIP:

Having consulted the Guidance on submitting pediatric development plans and pediatric studies, have you developed a Canadian pediatric development plan (C-PDP) for participating in the pilot?

O No
O Yes. To participate in the pilot, a C-PDP must be included with the NDS or SNDS at the time of filing. Including a C-PDP document constitutes participation.

7. For respondents who said “no” to participating in the pilot:

Please provide a brief explanation on why you do not wish to participate.

☐ Prefer not to answer

**For NDS filings, please stop here and include this survey with your submission.**



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**For SNDS filings only**

1. Does this drug already have an approved pediatric indication(s)?
   - ○ Yes
   - ○ No

2. Do the approved pediatric indication(s) align with all approved adult indication(s)?
   - ○ Yes
   - ○ No. Please identify all reasons why the approved pediatric indication(s) do not align with all approved adult indication(s):
     - ☐ Pediatric indication(s) for all adult indication(s) not possible or highly impracticable (for example, condition does not occur in pediatric populations)
     - ☐ Evidence that the drug would be ineffective and/or unsafe in pediatric populations
     - ☐ The drug does not present a significant therapeutic benefit over existing treatments for the pediatric population
     - ☐ Data to support pediatric indication(s) was previously submitted but the indication being sought was not approved
     - ☐ Pediatric studies are ongoing
     - ☐ Other (please explain):

3. Do the approved pediatric indication(s) span all pediatric age groups (birth up to 18 years)?
   - ○ Yes
   - ○ No. Please identify all the reasons for why the approved pediatric indication(s) do not span all pediatric age groups:
     - ☐ Pediatric indication(s) for all adult indication(s) not possible or highly impracticable (for example, condition does not occur in pediatric populations)
     - ☐ Evidence that the drug would be ineffective and/or unsafe in pediatric populations
     - ☐ The drug does not present a significant therapeutic benefit over existing treatments for certain pediatric populations
     - ☐ Data to support pediatric indication(s) for certain age groups was previously submitted but not approved
     - ☐ Pediatric studies are ongoing
     - ☐ Other (please explain):



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