This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Module 1.10 Paediatric development program

Paediatric population

1. Are you submitting data in this submission to support use in a paediatric population?

☐ Yes ☐ No

If Yes, please indicate the age ranges of children for which you are seeking approval in this application (tick boxes):

- Adolescents (12 to 17 years)* ☐ Yes ☐ No
- Children (2 to 11 years) ☐ Yes ☐ No
- Infants and toddlers (28 days to 23 months) ☐ Yes ☐ No
- Preterm or term Newborn Infants (less than 28 days) ☐ Yes ☐ No

*Upper age may vary in different submissions

European Union

2. **Concerning the European Union:** Have you submitted data in the European Union for any of the four paediatric age ranges listed in Question 1 for the use(s) in this application to TGA?

☐ Yes ☐ No

If Yes, which groups (tick boxes):

- Adolescents (12 to 17 years)* ☐ Yes ☐ No
- Children (2 to 11 years) ☐ Yes ☐ No
- Infants and toddlers (28 days to 23 months) ☐ Yes ☐ No
- Preterm or term Newborn Infants (less than 28 days) ☐ Yes ☐ No

*Upper age limit may vary between regulatory authorities

3. Do you have an agreed Paediatric Investigation Plan (PIP) in Europe?

☐ Yes ☐ No ☐ Currently under discussion with EMA

If Yes, what is the date on which you are first required to submit a report of a study conducted as part of the PIP?

Date:

If No, do you have a waiver from having to present a PIP in Europe?

☐ Yes ☐ No

Please record here the reason for the granting of the waiver:

United States of America

4. **Concerning the United States of America mandatory requirements:** Have you submitted data to the US Food and Drug Administration for any of the four paediatric age ranges listed in Question 1 for the use(s) in this application to TGA?

☐ Yes ☐ No

If Yes, which groups (tick boxes):

- Adolescents (12 to 17 years)* ☐ Yes ☐ No
- Children (2 to 11 years) ☐ Yes ☐ No
- Infants and toddlers (28 days to 23 months) ☐ Yes ☐ No
- Preterm or term Newborn Infants (less than 28 days) ☐ Yes ☐ No

*Upper age limit may vary between regulatory authorities

5. Do you have an agreed Pediatric Plan under the *Pediatric Research Equity Act* (PREA) in the USA?

☐ Yes ☐ No

If Yes, what is the date on which you are first required to submit a Paediatric Assessment (usually including a report of a study conducted as part of the Paediatric Plan)?

Date:

Do you have a waiver (full or partial) or deferral from having to submit a Pediatric Assessment in the USA?

☐ Yes ☐ No

Please record here the reason(s) for the granting of the waiver or deferral, if the waiver is partial (not a full waiver), please also record those indications for which the partial waiver has been granted:

6. **Concerning the United States of America *Best Pharmaceuticals for Children Act* (BPCA):** A company may gain additional market exclusivity in the United States of America if it completes the paediatric clinical studies set out in a Written Request (WR) issued by the US Food and Drug Administration. Has your company received a Written Request with respect to paediatric clinical studies for any of the uses in this submission to the TGA?

   ☐ Yes ☐ No