Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision[i]

Actives substances(s): Pritoxaximab, Setoxaximab

Latest Decision number(s): 1) P/308/2011

Corresponding PIP number(s): 1) EMEA-001134 PIP01-11

If the PIP has been submitted as part of a marketing authorisation application in order to comply with the requirements of Article 7 of the Paediatric Regulation (as a condition of the validation of the respective application) and a marketing authorisation was granted based on this application, then there is a legal obligation to complete that PIP. The same applies if there has been a successful post-authorisation application, where the PIP was included in order to comply with the requirements of Article 8 of the Paediatric Regulation.

Please confirm if any of the above applies:

Yes ☐ No ☒

If yes, it means that based on the Marketing Authorisation obtained at the end of that initial procedure or the successful post-authorisation application, as applicable, you are obliged to complete that PIP. That obligation cannot be cancelled by a unilateral decision, including by withdrawing the MA. Such PIP must be completed, unless it is modified in agreement with the PDCO by removing all outstanding PIP measures or granting a full product-specific waiver instead (upon relevant circumstances in accordance with the Paediatric Regulation). Non-completion of a binding PIP establishes noncompliance with the requirements of the Paediatric Regulation, which the European Medicines Agency has an obligation to report to the European Commission.

Please note that development of the medicinal product above in the following **condition(s)/indication(s)**:

Prevention of Shiga toxin-mediated complications resulting from Shiga toxin-producing bacterial infections.

☒ has been discontinued

for the following reason(s): (tick all that apply)

☐ (possible) lack of efficacy in adults

☐ (possible) lack of efficacy in children

☐ (possible) unsatisfactory safety profile in adults

☐ (possible) unsatisfactory safety profile in children

☒ commercial reasons (please specify: Strategic portfolio reprioritisation following inability to progress the US programme; development no longer financially viable)

☐ manufacturing / quality problems

☐ other regulatory action (please specify:)

☒ other reason (please specify: Feasibility constraints—regulatory feedback prevented initiation of the planned clinical programme; no viable path to MA identified)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation:

The MAH confirms permanent discontinuation of paediatric development for Shigamab (Pritoxaximab, Setoxaximab) under P/0308/2011 (historic reference EMEA-001134-PIP01-11), targeting the prevention of Shiga toxin-mediated complications resulting from Shiga toxin-producing bacterial infections. Following regulatory feedback received in the United States, the proposed clinical programme could not be initiated. As a consequence, and after internal portfolio review, the programme was deemed not financially viable and there is no feasible development path to an EU marketing authorisation. Therefore, development has ceased and no further paediatric activities are planned under this PIP. No paediatric subjects have been exposed under this PIP. We confirm that this PIP has not been included in any EU marketing authorisation application under Article 7, nor in any successful post-authorisation application under Article 8 of Regulation (EC) No 1901/2006; hence, no legal obligation to complete the PIP was triggered.

Name and signature of the PIP contact point:

Date: 12/03/2026

Contact for inquiries from interested parties:

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[i] This form will be published to the corresponding decision available on the website of the European Medicines Agency.