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

Actives substances(s): Sirukumab

Latest Decision number(s): 1) P/0150/2017

Corresponding PIP number(s): 1) EMEA-001043-PIP01-10-M03

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)**:

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

☒ 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:)

☐ manufacturing / quality problems

☒ other regulatory action (please specify: Withdrawal of the marketing authorisation application of Plivensia for the treatment of moderately to severely active rheumatoid arthritis in adult patients) (e.g. suspension, revocation of M.A.)

☐ other reason (please specify:)

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

Janssen Research & Development made the decision to terminate the sirukumab rheumatoid arthritis development program, and to withdraw the marketing authorization applications that were filed globally. Janssen maintains its belief in the efficacy and safety of sirukumab. However, the need for additional clinical data as requested by health authorities would result in significant delays to patient access to sirukumab in parts of the world. Given this, as well as the availability of other treatments targeting the IL-6 pathway, Janssen has made a global strategic decision to prioritize other assets in its portfolio. The MAA withdrawal letter to EMA was sent on 26 October 2017.

Name and signature of the PIP contact point:	Signature on file
Date:	21 March 2024

Contact for inquiries from interested parties:	Janssen-Cilag International NV
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[i] This form will be published to the corresponding decision available on the website of the European Medicines Agency.