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

Actives substances(s): Bemnifosbuvir

Latest Decision number(s): 1) P/0462/2023

Corresponding PIP number(s): 1) EMEA-002963-PIP01-21-M01

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 coronavirus disease 2019 (COVID-2019)

☒ 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:)

☐ other reason (please specify:)

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

Discontinuation of bemnifosbuvir (H0005889) pediatric development and request of withdrawal of the agreed PIP is linked to more global discontinuation of the development of the product in this indication (treatment of COVID-19) as the Phase 3 did not meet its objectives.

Of note, simultaneously to this request, the Sponsor is requesting the withdrawal of the intent to submit a MAA for Bemnifosbuvir for treatment of COVID-19.

Date: 19 December 2024

[i] This form will be published alongside the corresponding decision on the European Medicines Agency's website. Please ensure that this form does not contain any commercially confidential information and that the contact details for public enquiries are accurate on the website.