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

Actives substances(s): Respiratory Syncytial Virus PreF3 recombinant fusion protein (RSVPreF3)

Latest Decision number(s): 1) P/0098/2021

Corresponding PIP number(s): 1) EMEA-002821-PIP01-20

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 respiratory syncytial virus-associated lower respiratory tract illness through maternal immunisation

☒ 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, see below)

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

GSK was developing an RSV subunit vaccine for maternal use (RSVPreF3 maternal vaccine) that is based on the RSV fusion (F) protein stabilized in its prefusion conformation. In 2020, GSK initiated a phase 3 trial (RSV MAT-009) to assess the safety and efficacy of RSVPreF3 maternal vaccine against RSV-associated lower respiratory tract disease in infants born to women who had received the vaccine during pregnancy. In February 2022, the Independent Data Monitoring Committee for the RSV MAT-009 study observed an imbalance in the proportion of preterm births in the vaccine group as compared with the placebo group and recommended that study enrolment be paused. As a result, GSK voluntarily stopped the enrolment and vaccination of participants in all ongoing RSVPreF3 maternal vaccine studies (including the 2 PIP studies, i.e. RSV MAT-012 and RSV MAT-039) as a precautionary measure. GSK promptly informed the relevant regulatory authorities, the ethics committees at the trial sites, and the investigators. The findings regarding preterm birth led to the discontinuation by GSK of RSVPreF3 maternal vaccine development. Safety follow up of vaccinated participants from the vaccination trials (including the 2 PIP studies) continued until the end of the study as per protocol of each study. The last study (i.e. RSV MAT-015, a follow-up study to describe the safety of study participants who received RSVPreF3 maternal vaccination (any dose) or controls from previous RSV MAT studies; no study intervention was administered to participants in this study) of RSVPreF3 maternal vaccine was completed (last-participant last visit) on 15 January 2025.

No other safety signal has been observed among infant or maternal participants in any trial of RSVPreF3 maternal vaccine.

Date: 14 August 2025

Contact for inquiries from interested parties: GlaxoSmithKline Biologicals SA

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