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

Actives substances(s): Single-stranded 5' capped mRNA encoding the HAs of the influenza virus strains A/H1N1, A/H3N2, and B/Victoria and the N-terminal domain (NTD) and receptor binding domain (RBD) of the SARS-CoV-2 spike glycoprotein (mRNA-1083)

Latest Decision number(s): 1) P/0309/2024

Corresponding PIP number(s): 1) EMEA-003521-PIP01-23

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 Coronavirus disease 2019 (COVID-19)
- Prevention of influenza

☒ 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: No MAA is foreseen for PRD/0000433910. The adult and paediatric clinical development will advance for PRD/0000528909 only).

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

EMEA-003521-PIP01-23 was initiated to support the development of mRNA-1083 with a quadrivalent influenza composition: A/H1N1, A/H3N2, B/Y, and B/V. During the review of PIP EMEA-003521-PIP01-23, the WHO/CHMP recommended the removal of the B/Y strain from the composition of influenza vaccines for the 2024/2025 season. Consequently, the composition of mRNA-1083 was adjusted to a trivalent formulation for the influenza component: A/H1N1, A/H3N2, and B/V.

As a consequence, the paediatric clinical development of EMEA-003521-PIP01-23 has been discontinued to advance with the TIV formulation (EMA/PE/0000227301).

Date:	30 October 2025
Contact for inquiries from interested parties:	Moderna EMEA Medical Information
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[i] This form will be published to the corresponding decision available on the website of the European Medicines Agency.