To:

Head of Paediatric Medicines
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Recombinant respiratory syncytial virus vaccine

Invented name: MEDI7510

Latest Decision number(s): 1) P/0258/2016 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001966-PIP01-16 2) EMEA- 3) EMEA- 4) EMEA-

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

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

☒ has been discontinued

☐ has been suspended/put on long-term hold (with possible re-start at a later time)

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:) (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 / suspension:

MedImmune has decided to discontinue development of MEDI7510 based on results for the Phase 2b study that showed that the study did not meet its primary objective. This decision was not due to safety concerns.

Name and signature of the PIP contact point: Michael O'Flynn

Date: 14th October 2016

Contact for inquiries from interested parties:

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