

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): Purified antigen fractions of inactivated split virion Influenza
A/Indonesia/05/2005(H5N1) like strain used (PR8-IBCDC-RG2)
Invented name: Pumarix

Latest Decision number(s): 1) P/0088/2015 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000178-PIP01-07-M04 2) EMEA- 3) EMEA- 4)
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Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
prevention of influenza infection.

- ☒ 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: withdrawal of license and discontinuation of the clinical development)

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

The paediatric development for purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005(H5N1) like strain used (PR8-IBCDC-RG2) has been discontinued specifically for Pumarix due to the withdrawal of the Pumarix MAA in February 2015. Clinical development of Pumarix in both adult and paediatric populations has been discontinued in the EU. Please note that the studies in the PIP-178 are included in PIP-160 for 2 other registered Pandemic/Prepandemic Influenza vaccines -namely Adjuvanrix and Prepandrix, respectively. The clinical development in the paediatric population covered by PIP-160 for these two vaccines is continuing.

Name and signature of the PIP contact point: Anne Van Roosbroeck

Date: 21-08-2015

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