

To:

Head of Paediatric Medicines
European Medicines Agency
30 Churchill Place
London E14 5EU
United Kingdom
paediatrics@ema.europa.eu

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

Actives substances(s): Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H1N1/Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H3N2/Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B

Invented name: Flud and associated names

Latest Decision number(s): 1) P/208/2010 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-00149-PIP01-07-M02 2) EMEA- 3) EMEA- 4) EMEA-

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

Prevention of influenza in children and adolescents from 2 months to less than 18 years of age

☒ 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:

The Pediatric Use Medicinal Application for the Flud Pediatric (trivalent adjuvanted influenza vaccine) was withdrawn in February 2011. Since then, a quadrivalent adjuvanted seasonal influenza vaccine has been developed and is covered by PIP no. EMEA-001715-PIP. Seqirus therefore proposes to discontinue PIP-00149-PIP01-07-M02.

Name and signature of the PIP contact point: Signature on file

Date: 29 October 2018

Contact for inquiries from interested parties: pip.seq@seqirus.com

Telephone: --

Email: --