

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) inactivated, of H1N1, H3N2 and B strains recommended by WHO

Invented name: Optaflu

Latest Decision number(s): 1) P/0210/2012 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000124-PIP01-07-M02 2) EMEA- 3) EMEA-
4) EMEA-

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

Prophylaxis of influenza in children and adolescents aged 0 months to 17 year

☒ 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: Seqirus proposes that the above PIP be discontinued as the Optaflu MA has expired and the company has now developed a quadrivalent cell based influenza vaccine)

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

Following the request dated 28 June 2013 to put this PIP on long term hold, the company confirms that a quadrivalent cell-based influenza vaccine (Flucelvax Tetra) has been developed under PIP EMEA-002068-PIP01-16-M02. The relevant MAA has been submitted to the EMA on 31 October 2017 and the opinion is expected in December 2018. For this reason Seqirus proposes to discontinue PIP EMEA-000124-PIP01-07-M2.

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

Date: 19 October 2018

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

Telephone: -

Email: -