

To:
Head of Paediatric Medicines
European Medicines Agency
7 Westferry Circus
London E14 4HB
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 years

- ☐ 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: Novartis proposes that the above PIP plan be put on long-term hold until testing in the pediatric population be conducted with our Quadrivalent cell culture influenza vaccine that is under development.)

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

Novartis expects that licensure in children will not be granted on the basis of existing immunogenicity data and the current Pediatric Investigation Plan (PIP) for Optaflu. Novartis expects that efficacy data will be required to secure a pediatric indication and we plan to generate this data with our Quadrivalent cell culture influenza vaccine. A new PIP plan will be proposed and agreed with PDCO as part of our Quadrivalent vaccine development.

Name and signature of the PIP contact point: Kirstin van Lijden

Date: June 28, 2013

Contact for inquiries from interested parties: Kelly Lindert

Telephone: +1 6178718142

Email: kelly.lindert@novartis.com

