

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): Trivalent, seasonal, recombinant influenza hemagglutinin vaccine

Invented name: Flublok

Latest Decision number(s): 1) P/0173/2012 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001133-PIP01-11 2) EMEA- 3) EMEA- 4) EMEA-

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

Prevention of seasonal 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: change in influenza vaccine landscape made that Protein Sciences decided to develop a quadrivalent seasonal recombinant influenza hemagglutinin vaccine rather than carrying on with a trivalent one)

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

Protein Sciences planned to register a trivalent seasonal recombinant influenza hemagglutinin vaccine in EU. A pre-submission meeting with EMA held in October 2012, but ultimately no Marketing Authorization Application was submitted in EU, hence Flublok has never been authorised in EU. Protein Sciences made the strategic decision to develop a quadrivalent seasonal recombinant influenza hemagglutinin vaccine (planned to be registered in EU in the coming years).

Name and signature of the PIP contact point: Lisa M. Dunkle, MD

Date: 22Mar2018

Contact for inquiries from interested parties: Lisa M Dunkle, MD

Telephone: 203-599-6064, ext 153

Email: lisa.dunkle@sanofi.com