EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals

## Procedural steps taken and scientific information after the authorisation



| No | Scope | Opinion/ Notification[1] issued on | Commission Decision Issued[2] / amended on | Product Information affected[3] | Summary |
|---|---|---|---|---|---|
| IB/0017 | B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data | 23/06/2010 | n/a | | |
| II/0013 | Change(s) to shelf-life or storage conditions | 24/09/2009 | 05/11/2009 | SPC | Extension of shelf life to 2 years. |
| II/0008 | To introduce some changes in the manufacturing process for the adjuvant emulsion at the bulk stage.<br><br>Change(s) to the manufacturing process for the finished product | 24/09/2009 | 05/10/2009 | | |
| II/0015 | To introduce some changes for the storage of the antigen.<br><br>Change(s) to container | 24/09/2009 | 05/10/2009 | | |
| IB/0016 | 42_a_01_Change in shelf-life of finished product - as packaged for sale | 30/09/2009 | n/a | | |

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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| II/0012 | To introduce some changes in the manufacturing site for the production of the active substance.<br><br>Quality changes | 20/08/2009 | 16/09/2009 | | |
| II/0011 | To introduce the use of alternative shipping containers to the manufacturing process for the active substance.<br><br>Quality changes | 20/08/2009 | 16/09/2009 | | |
| IB/0014 | 13_b_Change in test proc. for active substance - other changes (replacement/addition) | 11/09/2009 | n/a | | |
| II/0007 | To update sections 4.2, 4.4 and 5.1 of the SPC to include the possibility of a booster dose after primary immunisation with two doses of the marketing authorisation holder's (MAH) prepandemic vaccine containing antigen from the same subtype, based on data from clinical trials. The PL was updated accordingly.<br><br>Paediatrics to validate,<br>Update of Summary of Product Characteristics and Package Leaflet | 29/05/2009 | 07/07/2009 | SPC, PL | Based on immunogenicity and safety data from clinical trials, the product information was updated to reflect that a single dose of Pandemrix might be given to subjects who have previously received one or two doses of the MAH's AS03 adjuvanted prepandemic influenza vaccines. It has to be noted that the data are specific to the administration of H5N1 vaccine of a clade following one or two doses of H5N1 of a different clade. |
| II/0001 | To extend the therapeutic indication to include treatment in subjects aged 61 years and above based on clinical trial data. Annex II and the PL were updated accordingly. The marketing authorisation holder took the opportunity to introduce minor corrections in the SPC and labeling and to correct the contact details for Cyprus, Denmark, Latvia and Slovakia in the PL.<br><br>Extension of Indication | 29/05/2009 | 07/07/2009 | SPC, PL | Please refer to the Scientific Discussion: Prepandemic-Influenza-Vaccine-H-C-1015-II-01-AR |
| II/0002 | To update section 5.1 of the SPC regarding the interval between 2 doses for the primary | 29/05/2009 | 07/07/2009 | SPC, PL | In a clinical trial, two doses of A/Vietnam AS03 adjuvanted vaccine were needed to meet and exceed all three CHMP criteria |

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| | schedule vaccination based on data from a clinical trial. The PL was updated to reflect the results of user testing.<br><br>Update of Summary of Product Characteristics and Package Leaflet | | | | for responses to homologous virus. The results were observed when the two doses were given either 21 days apart or 6 months apart.<br>A single dose of A/Vietnam AS03 adjuvanted vaccine followed by a dose of A/Vietnam or A/Indonesia AS03 adjuvanted vaccine at Month 6 elicited haemagglutinin inhibition responses to homologous and heterologous booster strains that met and exceeded the CHMP criteria at Month 6 + 7 days post-boost with further increments at Month 6 + 21 days.<br>Therefore based on immunogenicity and safety data, the product information was updated to reflect that two doses of AS03-adjuvanted vaccine given 6 months apart give comparable immune responses after the second dose to two doses given 21 days apart.<br>The PL was updated further to a test performed to increase its readability. |
| II/0010 | To introduce a change in the manufactuirng process of the H5N1 antigen active substance.<br><br>Change(s) to the manufacturing process for the active substance | 25/06/2009 | 01/07/2009 | | |
| II/0009 | To introduce some changes to the manufacturing process of the antigen H5N1.<br><br>Change(s) to the manufacturing process for the active substance | 25/06/2009 | 01/07/2009 | | |
| II/0006 | To introduce an additional site for the manufacturing of the adjuvant.<br><br>Update of or change(s) to the pharmaceutical documentation | 23/04/2009 | 15/05/2009 | | |
| IA/0005 | 04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.) | 05/02/2009 | n/a | Annex II | |
| IB/0003 | 42_a_01_Change in shelf-life of finished product - as packaged for sale | 05/12/2008 | n/a | | |