EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pandemic Influenza Vaccine H5N1 Baxter

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IAIN/0032	A.1 - Administrative change - Change in the name and/or address of the MAH	01/02/2023		SmPC, Labelling and PL	
IAIN/0031	A.1 - Administrative change - Change in the name and/or address of the MAH	25/04/2022		SmPC, Labelling and	

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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				PL	
PSUSA/2282/202108	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, Vero cell derived, inactivated)	07/04/2022	n/a		PRAC Recommendation - maintenance
PSUSA/2282/202008	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, Vero cell derived, inactivated)	09/04/2021	n/a		PRAC Recommendation - maintenance
PSUSA/2282/201908	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, Vero cell derived, inactivated)	12/03/2020	n/a		PRAC Recommendation - maintenance
PSUSA/2282/201808	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, Vero cell derived, inactivated)	14/03/2019	n/a		PRAC Recommendation - maintenance
T/0026	Transfer of Marketing Authorisation	23/11/2018	12/12/2018	SmPC, Labelling and PL	
PSUSA/2282/201708	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, Vero cell derived, inactivated)	12/04/2018	n/a		PRAC Recommendation - maintenance
T/0024	Transfer of Marketing Authorisation	10/03/2017	24/03/2017	SmPC, Labelling and PL	
PSUSA/2282/201608	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, Vero cell derived, inactivated)	09/03/2017	n/a		PRAC Recommendation - maintenance

PSUSA/2282/201508	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, Vero cell derived, inactivated)	17/03/2016	n/a		PRAC Recommendation - maintenance
T/0021	Transfer of Marketing Authorisation Transfer of Marketing Authorisation	05/11/2015	27/11/2015	SmPC, Labelling and PL	Transfer of the Marketing Authorisation from Baxter AG to Nanotherapeutics Bohumil s.r.o.
PSUSA/2282/201408	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, Vero cell derived, inactivated)	12/03/2015	n/a		PRAC Recommendation - maintenance
PSUV/0019	Periodic Safety Update	09/10/2014	n/a		PRAC Recommendation - maintenance
R/0016	Renewal of the marketing authorisation.	20/03/2014	14/05/2014		
PSUV/0017	Periodic Safety Update	10/04/2014	n/a		PRAC Recommendation - maintenance
II/0015	Extension of Indication to include new population (paediatric) for Pandemic Influenza Vaccine H5N1 Baxter. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC were updated in order to include the new efficacy and safety information. The Package Leaflet and Labelling are updated in accordance. Furthermore, the PI is being brought in line with the latest QRD template version 9 and with the SmPC guideline and Core SmPC for pandemic vaccines. C.I.6.a - Change(s) to therapeutic indication(s) -	24/10/2013	25/11/2013	SmPC, Annex II, Labelling and PL	Please refer to the scientific discussion of the Assessment Report Pandemic influenza vaccine H5N1 Baxter-H-1200-II-15-VAR-en.

	Addition of a new therapeutic indication or modification of an approved one				
II/0014	Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product	27/06/2013	n/a		
IB/0013	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	11/02/2013	n/a		
IG/0214	A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	14/09/2012	n/a		
IAIN/0011	C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the safety database	24/04/2012	n/a		
II/0006	To add pre-filled syringes as an alternative primary container and presentation for the finished product.	16/02/2012	26/03/2012	SmPC and Labelling	

	B.II.e.1.b.2 - Change in immediate packaging of the finished product - Type of container - Sterile medicinal products and biological/immunological medicinal products				
II/0005	To introduce an alternative filling/ finishing site for the final Drug Product. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/immunological medicinal products.	15/03/2012	15/03/2012		
II/0004	To add an alternative unit at the manufacturing site for the finished product B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/immunological medicinal products.	15/03/2012	n/a		
II/0008	To introduce a change to extraneous agent testing of the active substance. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Change (replacement) to a biological/immunological/ immunochemical test method or a method using a	16/02/2012	16/02/2012		

	biological reagent for a biological AS				
IB/0009	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	17/01/2012	n/a		
IB/0007	B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line)	17/01/2012	n/a		
IA/0010	A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS	05/01/2012	n/a		
II/0003/G	This was an application for a group of variations. Update of the SmPC via a group of 3 type II variations to: 1) amend sections 4.2, 4.8 and 5.1 based on the latest immunogenicity and safety results on primary vaccination, cross-reactivity, persistence and booster from the phase III study 810705 conducted in adults, elderly and specified risk groups. The PL section 4 was revised accordingly; 2) include in sections 4.4 a class warning (Vero cell derived origin) and in section 4.8 the correspondent adverse reactions based on information available	17/11/2011	19/12/2011	SmPC, Annex II, Labelling and PL	

	from the related vaccine Celvapan. Sections 2 and 4 of the PL were revised accordingly; 3) update section 5.3 and 4.6 to reflect information from the non-clinical DART studies on pregnancy and safety. The PL was updated accordingly. The MAH took this opportunity to revise the PI based on the latest QRD template and formatting, including addition of information on lack of pediatric data in section 4.4 of the SmPC and section 3 of the PL and revision of the contact details for the local representatives. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
II/0002	To introduce an alternative manufacturing site for the filling of the final drug product. Quality changes	21/01/2010	03/02/2010		
II/0001	To change the batch size of the formulation and filling process of the final drug product. Quality changes	21/01/2010	03/02/2010		