



Vepacel

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification ¹ issued on	Commission Decision result/ ² recommended on	Product Information affected ³	Summary
T/0019	Transfer of Marketing Authorisation	23/11/2018	11/01/2019	SmPC, Labelling and PL	
PSUSA/2282/201708	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated), prepandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated)	12/04/2018	n/a		PRAC Recommendation - maintenance

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).



T/0017	Transfer of Marketing Authorisation	10/03/2017	03/04/2017	SmPC, Labelling and PL	
PSUSA/2282/ 201608	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated), prepandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated)	09/03/2017	n/a		PRAC Recommendation - maintenance
R/0015	Renewal of the marketing authorisation.	10/11/2016	04/01/2017	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Vepacel in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/2282/ 201508	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated), prepandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated)	17/03/2016	n/a		PRAC Recommendation - maintenance
T/0013	Transfer of Marketing Authorisation	05/11/2015	30/11/2015	SmPC, Labelling and PL	
IAIN/0012/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH C.I.8.a - Introduction of new changes to a summary of Pharmacovigilance System - Changes in OPPV	02/06/2015	30/11/2015	SmPC, Labelling and PL	

	(including contact details) and/or changes in the PSMF location				
PSUSA/2282/201408	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated), prepandemic influenza vaccine (H5N1) (whole virion, vero cell derived, inactivated)	12/03/2015	n/a		PRAC Recommendation - maintenance
PSUV/0010	Periodic Safety Update	09/10/2014	n/a		PRAC Recommendation - maintenance
PSUV/0009	Periodic Safety Update	10/04/2014	n/a		PRAC Recommendation - maintenance
II/0007	<p>Extension of Indication to include the paediatric population for Vepacel. As a consequence, sections 4.1, 4.2, 4.8 and 5.1 of the SmPC were updated in order to include new safety and efficacy information. The Labelling and Package Leaflet are updated in accordance. In addition, the MAH took the opportunity to update the list of local representatives in the Package Leaflet. Furthermore, the PI is being brought in line with the latest QRD template version 9, the SmPC guideline and the Core SmPC for pandemic vaccines.</p> <p>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one</p>	24/10/2013	25/11/2013	SmPC, Annex II, Labelling and PL	Please refer to the scientific discussion of the Assessment Report Vepacel-H-2089-II-07-VAR-en.
IB/0008	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	13/08/2013	25/11/2013	SmPC	

II/0006	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/0005	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	08/02/2013	n/a		
II/0002	To add an additional primary container for the finished product. 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	19/07/2012	4/10/2012	SmPC, Labelling and PL	
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		
IB/0001	B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a	08/05/2012	n/a		

	biological/immunological AS is increased/decreased without process change (e.g. duplication of line)				
IAIN/0003	C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the safety database	30/04/2012	n/a		

Medicinal product no longer authorised