Foclivia

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
II/0081	Extension of indication to include children from 6 months to less than 18 years of age for Foclivia, based on final results from study V87_30; this is a phase 2, randomized, observer-blind, multicenter study to evaluate the immunogenicity and safety of several doses of antigen and MF59 adjuvant content	20/07/2023	16/08/2023	SmPC, Annex II and PL	Please refer to Scientific Discussion 'Foclivia 001208-II-0081'.

[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).

	in a monovalent H5N1 pandemic influenza vaccine in healthy pediatric subjects 6 months to less than 9 years of age. As a consequence, sections 4.2, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 4.11 of the RMP has been agreed. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and to bring it in line with the latest QRD template. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
PSUSA/10008 /202210	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	12/05/2023	n/a		PRAC Recommendation - maintenance
II/0079	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	30/03/2023	n/a		
IB/0080	B.II.z - Quality change - Finished product - Other variation	03/11/2022	n/a		
WS/2341	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.2.a - Change to importer, batch release	29/09/2022	n/a		

	arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
WS/2248/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 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 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	10/06/2022	n/a		
PSUSA/10008 /202110	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	10/06/2022	n/a		PRAC Recommendation - maintenance

WS/2236/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	02/06/2022	n/a		
WS/2151	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of the RMP (part I, II, III, IV, V and VI) for AFLUNOV and FOCLIVIA in order to align the list of safety concerns for the products. The modules 'Epidemiology of the indication and target population' and 'Identified and potential risks' and the section of missing information are updated. Some potential risks have been reclassified following the definition as per GVP Module V rev.2. RMP version 4.0 was approved with this variation. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH	05/05/2022	n/a		

	where significant assessment is required				
IA/0077	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/04/2022	n/a		
WS/2226/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	31/03/2022	27/02/2023	SmPC, Annex II and PL	
IA/0072	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	09/12/2021	n/a		
WS/2178/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	09/12/2021	n/a		

	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place				
WS/2152	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	18/11/2021	n/a		
WS/2167	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	11/11/2021	n/a		

	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation				
IB/0066/G	This was an application for a group of variations. B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	13/08/2021	n/a		
IA/0067	A.7 - Administrative change - Deletion of manufacturing sites	04/08/2021	n/a		
WS/1985	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	01/07/2021	n/a		
PSUSA/10008 /202010	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	10/06/2021	n/a		PRAC Recommendation - maintenance

IA/0065	A.7 - Administrative change - Deletion of manufacturing sites	23/02/2021	22/11/2021	Annex II and PL	
WS/1958/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	10/12/2020	n/a		
WS/1982	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	03/12/2020	n/a		
II/0058	Update of sections 2, 4.2-4.8, 5.1 ,6.4 and 6.5 of the SmPC based on data obtained from two clinical trials (V87_25 and V87_26) already assessed and approved for Aflunov, the corresponding H5N1 Zoonotic Influenza Vaccine (procedure EMEA/H/C/002094/II/0044/G approved in June	26/11/2020	22/11/2021	SmPC, Labelling and PL	As Aflunov and Foclivia licenses are based on the same H5N1 study data, the conclusions approved for Aflunov in the 2019 within EMEA/H/C/002094/II/44 also apply to Foclivia present variation. In the current variation Foclivia SmPC has been modified to align the text with text approved for Aflunov in the named procedure considering

	2019) in order to align both products. In addition, the MAH took the opportunity to also add in section 5.1 data from study V87P2 and study V87P11 (A/Turkey/turkey/1/2005) included for the RMP of both products and in the label of Aflunov for further alignment; the Package Leaflet and Labelling are updated accordingly. Finally, the Marketing authorization holder (MAH) make additional changes based on the most recent EU Guidelines and some additional minor editorial corrections. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				data from two H5N1 studies (V87P2 and V87P11, A/Turkey/turkey/1/2005).
IA/0062/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	06/11/2020	n/a		
IA/0060/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name	20/10/2020	n/a		

	and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)				
WS/1796/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	03/09/2020	n/a		
WS/1860	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	16/07/2020	n/a		
WS/1823/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No	02/07/2020	n/a		

	1234/2008. B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP 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				
IA/0056/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	20/05/2020	n/a		
PSUSA/10008 /201910	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), prepandemic influenza	14/05/2020	n/a		PRAC Recommendation - maintenance

	vaccine (H5N1) (surface antigen, inactivated, adjuvanted)				
IB/0053	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	27/02/2020	n/a		
IB/0051	B.II.g.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	17/01/2020	n/a		
IB/0050	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	09/12/2019	n/a		
IAIN/0049	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	22/10/2019	28/11/2019	Annex II and PL	
IAIN/0048	A.1 - Administrative change - Change in the name and/or address of the MAH	06/09/2019	28/11/2019	SmPC, Labelling and PL	
WS/1628	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement	25/07/2019	n/a		

	or addition) for the AS or a starting material/intermediate				
WS/1600/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	27/06/2019	28/11/2019	SmPC and PL	
IAIN/0047	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	16/05/2019	n/a		
PSUSA/10008 /201810	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	16/05/2019	n/a		PRAC Recommendation - maintenance
IB/0045	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS -	03/05/2019	n/a		

	Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place				
WS/1562/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits	02/05/2019	n/a		
II/0040/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes	28/03/2019	n/a		
WS/1530/G	This was an application for a group of variations following a worksharing procedure according to	28/03/2019	n/a		

	Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes 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/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				
WS/1538	This was an application for a variation following a worksharing procedure according to Article 20 of	13/12/2018	n/a		

	Commission Regulation (EC) No 1234/2008. B.II.g.2 - Introduction of a post approval change management protocol related to the finished product				
II/0038/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes C.I.z - Changes (Safety/Efficacy) of Human and	13/12/2018	28/11/2019	SmPC, Labelling and PL	

	Veterinary Medicinal Products - Other variation				
WS/1368/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	21/06/2018	n/a		
PSUSA/10008 /201710	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	17/05/2018	n/a		PRAC Recommendation - maintenance
WS/1311/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.c - Changes in the manufacturing process of	08/03/2018	n/a		

	the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol 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				
WS/1323	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	01/02/2018	n/a		
WS/1214	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	19/10/2017	n/a		
WS/1165	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.a - Changes in the manufacturing process of	20/07/2017	n/a		

	the AS - Minor change in the manufacturing process of the AS				
WS/1143	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS	20/07/2017	n/a		
WS/1170	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	06/07/2017	n/a		
II/0027	B.II.b.3.e - Change in the manufacturing process of the finished or intermediate product - Introduction or increase in the overage that is used for the AS	22/06/2017	n/a		
WS/1145/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. A.7 - Administrative change - Deletion of	15/06/2017	n/a		

	manufacturing sites B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol B.I.c.1.z - Change in immediate packaging of the AS - Other variation				
IA/0032/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised	01/06/2017	n/a		
PSUSA/10008 /201610	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	05/05/2017	n/a		PRAC Recommendation - maintenance
IB/0026	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other	17/03/2017	n/a		

	changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
II/0023/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	15/12/2016	n/a		
IAIN/0024/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or	03/11/2016	09/01/2017	SmPC, Annex II, Labelling and PL	

	manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.7 - Administrative change - Deletion of manufacturing sites				
IB/0022/G	This was an application for a group of variations. B.I.a.1.a - Change in the manufacturer of AS or of a	14/06/2016	n/a		

	starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol				
PSUSA/10008 /201510	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	13/05/2016	n/a		PRAC Recommendation - maintenance
IB/0019/G	This was an application for a group of variations. B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with	26/02/2016	n/a		

	its corresponding test method B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation				
IAIN/0021/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	05/02/2016	09/01/2017	Annex II and PL	
PSUSA/10008 /201410	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	21/05/2015	28/07/2015		Please refer to Aflunov PSUSA/00010008/201410 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
T/0017	Marketing Authorisation Transfer from Novartis Vaccines and Diagnostics S.r.l. to Novartis Vaccines Influenza S.r.l.	21/04/2015	27/05/2015	SmPC, Labelling and PL	

	Transfer of Marketing Authorisation				
II/0015/G	This was an application for a group of variations. B.I.c.1.b - Change in immediate packaging of the AS - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological ASs B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol B.II.h.1.b.1 - Update to the Adventitious Agents Safety Evaluation information - Replacement of obsolete studies related to manufacturing steps and adventitious agents already reported in the dossier - with modifications of risk assessment 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	21/05/2015	n/a		
IAIN/0018	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	28/04/2015	n/a		
R/0012	Renewal of the marketing authorisation.	25/04/2014	27/06/2014	Annex II	On the basis of the available clinical data for influenza A/H5N1 and A/H1N1 strains submitted to CHMP since MA, the benefit-risk balance of Foclivia remains favourable.

					Foclivia is not marketed since it is a mock-up pandemic vaccine. The knowledge of the safety of Foclivia vaccine is based, until now, on limited data coming from clinical studies. Most of the available evidence is based on the experience gathered with the pandemic vaccine A/H1N1, Focetria. Due to the type of vaccine under evaluation and taking into account that it can be used only in a pandemic situation after a strain change, it is expected that in the next five years the generation of new evidence from post-marketing experience is very unlikely. Thus, the CHMP recommends that the renewal be granted with unlimited validity. The MA will remain under exceptional circumstances.
II/0008/G	This was an application for a group of variations. Update of sections 4.3, 4.4, 4.6, 4.8 and 5.1 of the SmPC with data on convulsion, to include barium sulphate among the trace residues, data on pregnancy with H1N1v, results from a cumulative review on thrombocytopenia and data on immunogenicity and safety from study V111_03 in children with H1N1v. The Package Leaflet is updated accordingly. Furthermore, the PI is being brought in line with the latest QRD template version 9. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	22/05/2014	27/05/2015	SmPC, Annex II, Labelling and PL	This group of three variations proposed the update of the Foclivia PI with data generated with other adjuvanted H5N1 or H1N1 vaccines (Aflunov and Focetria respectively). The data is the following: i) data indicating that some cases of convulsion with and without fever have been reported in subjects vaccinated with H1N1v and thus patients need to be informed; ii) barium sulphate was included among the trace residues due to the associated hypersensitivity risks; iii) data on pregnancy with H1N1v was included to show that there is no direct or indirect harmful effects from vaccination with H1N1v during pregnancy; iv) results from a cumulative review on thrombocytopenia was included to alert that some cases have been detected with seasonal influenza vaccines; v) and data on immunogenicity and safety from study V111_03 in children with H1N1v was added overall supporting the positive benefit/risk profile of the vaccine.

	data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUV/0013	Periodic Safety Update	08/05/2014	n/a		PRAC Recommendation - maintenance
II/0011/G	This was an application for a group of variations. Change in the name and/or address of a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or manufacturer of a novel excipient. Changes to in-process tests or limits applied during the manufacture of the active substance. Changes in test procedure for the active substance or starting material/reagent/intermediate. Change in the manufacturer of the active substance or of a starting material/reagent/intermediate. Changes in the manufacturing process of the active substance. Change in the specification parameters of the active substance, starting material/intermediate/reagent. Change in immediate packaging of the active substance. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or	25/04/2014	27/06/2014	Annex II	

	manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological 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 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 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				

	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation 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 B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.c.1.z - Change in immediate packaging of the AS - Other variation				
IG/0426	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	11/04/2014	n/a		
II/0010/G	This was an application for a group of variations. Replacement or addition of a manufacturing site, change in immediate packaging, change in the storage period, change in test procedures and in the specification parameters and/or limits for the adjuvant. 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	20/02/2014	n/a		

	release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.I.c.1.b - Change in immediate packaging of the AS - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological ASs B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS 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 B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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				
IB/0009/G	This was an application for a group of variations. B.II.d.2.z - Change in test procedure for the finished product - Other variation	04/02/2014	n/a		

	B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method				
II/0007	Update of sections 4.2, 4.8 and 5.1 of the SmPC following CHMP request in PSU012 to include data on safety and immunogenicity from the pediatric study V87P6. Based on the SmPC guideline section 4.2 was also restructured and a standard statement on pediatric studies deferral was added in section 5.1. The DDPS details in Annex II were revised based on the QRD template. The MAH took this opportunity to include editorial corrections in sections 4.8 and 5.1 of the SmPC and in sections 1 and 4 of the PL for improved clarity. C.I.3.b - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under Article 45/46, or amendments to reflect a Core SPC - Change(s) with new additional data submitted by the MAH	16/02/2012	21/03/2012	SmPC, Annex II and PL	The adverse reactions from clinical trial V87P6 in children aged 6 months to 17 years were included in section 4.8 of the SmPC, showing a safety profile similar to a seasonal vaccine and an increased reactogenicity after the booster dose and in the older age groups. Section 4.2 was restructured in line with the SmPC guideline and to improve clarity. Data from the pediatric clinical trial V87P6 were included in section 5.1 of the SmPC to show that high levels of antibodies were achieved after two vaccinations in all age groups. The standard statement on deferral of pediatric studies was added to section 5.1 based on the SmPC guideline. Editorial changes for improved clarity were introduced in sections 1 and 4 of the PL, and sections 4.8 and 5.1 of the SmPC. The DDPS version number in Annex II was deleted based on the QRD template.

II/0006	Update of section 4.4 of the SmPC to add a warning on the limited cross-reactivity and of sections 4.8 and 5.1 to include safety and immunogenicity data, data on cross-protection and antibody persistence from clinical studies V87P1 and V87P13 following CHMP request in RMP018. The MAH took this opportunity to include the date of first authorisation in section 8 and the MA numbers in section 9 of the SmPC and in the labelling. C.I.3.b - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under Article 45/46, or amendments to reflect a Core SPC - Change(s) with new additional data submitted by the MAH	16/02/2012	21/03/2012	SmPC and Labelling	A warning was included in section 4.4 that only some level of cross-protection was observed against related H5N1 virus variants in clinical trials. Sections 4.8 and 5.1 of the SmPC were updated to include safety and immunogenicity data, data on cross-protection and antibody persistence from clinical studies V87P1 and V87P13 using two doses of vaccine (A/Vietnam/1194/2004 H5N1 - 7.5 or 15 ug HA/dose) in adults and elderly, following CHMP request from the post-authorisation commitment RMP018.
IA/0003/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the safety database C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the	10/08/2010	n/a	Annex II	

	DD C.I.9.f - Changes to an existing pharmacovigilance system as described in the DDPS - Deletion of topics covered by written procedure(s) describing pharmacovigilance activities C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities				
IB/0001	To update the dossier to correctly include the contract laboratory Microsafe Services from Millipore in the relevant section 3.2.S.2.1 - Manufacturer. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	09/07/2010	n/a		
IA/0002	To change the name from Novartis Vaccines and Diagnostics GmbH & Co.KG to Novartis Vaccines and Diagnostics GmbH for a manufacturer responsible for production of adjuvant bulk. 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)	07/05/2010	n/a		