EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FLUENZ

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
PSUV/0060	Periodic Safety Update	10/07/2014	n/a		PRAC Recommendation - maintenance
IG/0405	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or change in the PSMF location	26/02/2014	n/a		
PSUV/0055	Periodic Safety Update	09/01/2014	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).

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IB/0058	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	19/12/2013	n/a		
IAIN/0057	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	22/10/2013	n/a		
IAIN/0056	C.I.12 - Inclusion or deletion of black symbol and explanatory statements for medicinal products in the list of medicinal products that are subject to additional monitoring	21/10/2013		SmPC and PL	
II/0053	Annual Strain Update B.I.a.5.a - Changes to the AS of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza	26/07/2013	14/08/2013	SmPC, Labelling and PL	Seasonal update of the composition of the strains to those officially recommended by WHO and CHMP for the season 2013/2014, and these are the following: A/California/7/2009 (H1N1) pdm09-like strain A/Victoria/361/2011 (H3N2)-like strain B/Massachusetts/2/2012 (B-strain)-like strain
N/0054	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/07/2013		PL	
IB/0052/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied	02/07/2013	n/a		

	during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation				
IB/0049	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	24/06/2013		SmPC and PL	
IB/0043/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS A.7 - Administrative change - Deletion of manufacturing sites	15/05/2013	n/a		
IB/0044	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	07/05/2013	n/a		
IA/0045	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	30/04/2013	n/a		
II/0037	Changes in the manufacturing process of the active substance. 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 medicinal product and is not related to a protocol	25/04/2013	25/04/2013		

IB/0042	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	06/03/2013	n/a		
IB/0039	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/03/2013		SmPC, Annex II, Labelling and PL	
IA/0041	C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	27/02/2013	n/a		
IB/0040	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	19/02/2013	n/a		
IA/0038	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)	17/01/2013	n/a		
IB/0034	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	17/01/2013	n/a		
IA/0035	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)	10/12/2012	n/a		
II/0031	Annual Strain Update	03/08/2012	28/08/2012	SmPC,	Seasonal update of the composition of the strains to those

	B.I.a.5.a - Changes to the AS of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza			Labelling and PL	officially recommended by WHO and CHMP for the season 2012/2013, and these are the following: A/California/7/2009 (H1N1) pdm09-like strain; A/Victoria/361/2011 (H3N2)-like strain; B/Wisconsin/1/2010 (B-strain)-like strain
IB/0021/G	This was an application for a group of variations. B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	16/07/2012	n/a		
IB/0032	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/07/2012	12/07/2012	Annex II	
IB/0018	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	12/07/2012	n/a		
IB/0025	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	27/06/2012	n/a		
IAIN/0033	B.I.b.1.a - Change in the specification parameters and/or limits of the AS, starting material/intermediate/reagent - Tightening of specification limits for medicinal products subject to Official Batch Release	25/06/2012	n/a		

IAIN/0030/G	This was an application for a group of variations. 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 DD C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	20/06/2012	n/a		
IB/0029	B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	20/06/2012	n/a		
IB/0028	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	20/06/2012	n/a		
IB/0026	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	14/06/2012	n/a		
N/0027	Minor change in labeling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/06/2012	24/08/2012	PL	
IB/0024	B.I.b.2.z - 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	25/05/2012	n/a		

II/0016	to introduce changes to the manufacturing process 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 biological reagent for a biological AS	24/05/2012	24/05/2012		
IB/0020	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	23/05/2012	n/a		
IB/0019/G	This was an application for a group of variations. 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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for 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	23/05/2012	n/a		
IA/0022	B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)	11/05/2012	24/08/2012	SmPC, Labelling and PL	
IA/0023	B.I.a.4.a - Change to in-process tests or limits applied	01/05/2012	n/a		

	during the manufacture of the AS - Tightening of in-process limits				
II/0014	Addition of two test methods for 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 biological reagent for a biological AS	16/02/2012	16/02/2012		
IB/0013/G	This was an application for a group of variations. B.I.a.4.f - Change to in-process tests or limits applied during the manufacture of the AS - Addition or replacement of an in-process test as a result of a safety or quality issue B.I.a.4.f - Change to in-process tests or limits applied during the manufacture of the AS - Addition or replacement of an in-process test as a result of a safety or quality issue	20/12/2011	n/a		
IB/0015	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	18/11/2011	n/a		
IB/0012/G	This was an application for a group of variations. 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	18/11/2011	n/a		

	its corresponding test method B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation				
II/0008/G	This was an application for a group of variations. To introduce changes to the test procedures 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 biological reagent for a biological AS B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/10/2011	20/10/2011		
IB/0011/G	This was an application for a group of variations. 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.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	17/10/2011	n/a		
II/0003/G	This was an application for a group of variations. To introduce changes to the manufacture of the active substance and to change the testing plan to accommodate the changes. B.I.a.2.b - Changes in the manufacturing process of	22/09/2011	22/09/2011		

	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.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation				
II/0009	To introduce changes to the mixing of the blended bulk finished product. B.II.b.3.b - Change in the manufacturing process of the finished product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	21/07/2011	21/07/2011		
II/0004	to introduce changes to the manufacture of the active substance. 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	23/06/2011	23/06/2011		
II/0001	To introduce changes to the manufacture of the active substance. 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	23/06/2011	23/06/2011		

	the AS and/or the FP				
IA/0010	A.7 - Administrative change - Deletion of manufacturing sites	07/06/2011	n/a		
IB/0006	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	18/05/2011	n/a		
IB/0005	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	18/05/2011	n/a		
IB/0002/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.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.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	10/05/2011	n/a		