Pandemic influenza vaccine H5N1 AstraZeneca

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
R/0071	Renewal of the marketing authorisation.	22/02/2024	19/04/2024	SmPC, Annex II and PL	The CHMP, having reviewed the available information on the status of the fulfilment of Specific Obligations and having confirmed the positive benefit risk balance, is of the opinion that the quality, safety and efficacy of this medicinal product continue to be adequately and sufficiently demonstrated and therefore recommends the

[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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					renewal of the conditional MA for Pandemic influenza vaccine H5N1 AstraZeneca, subject to the Specific Obligations and Conditions as laid down in Annex II to the opinion.
PSUSA/10501 /202305	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (live attenuated, nasal)	11/01/2024	n/a		PRAC Recommendation - maintenance
WS/2581/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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation 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	30/11/2023	n/a		
WS/2579/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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished	09/11/2023	n/a		

	product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
WS/2578	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.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	09/11/2023	n/a		
IA/0069	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	11/10/2023	n/a		
IB/0065/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.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	02/08/2023	n/a		
PSUSA/10501 /202211	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (live attenuated, nasal)	08/06/2023	n/a		PRAC Recommendation - maintenance
WS/2466	This was an application for a variation following a	01/06/2023	n/a		

	worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
WS/2454	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.e - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a specification parameter which may have a significant effect on the overall quality of the AS and/or the FP	25/05/2023	n/a		
WS/2447/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.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation	14/04/2023	n/a		
IA/0064	A.7 - Administrative change - Deletion of manufacturing sites	22/03/2023	n/a		
R/0057	Renewal of the marketing authorisation.	26/01/2023	09/03/2023		

WS/2385/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.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.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method	09/02/2023	n/a		
WS/2391	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 or addition) for the AS or a starting material/intermediate	02/02/2023	n/a		
WS/2388/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No	26/01/2023	n/a		

	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.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method				
PSUSA/10501 /202205	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (live attenuated, nasal)	12/01/2023	n/a		PRAC Recommendation - maintenance
WS/2340/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 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	10/11/2022	n/a		

IA/0055	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	01/11/2022	n/a		
IB/0054	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	04/10/2022	09/03/2023	SmPC, Labelling and PL	
IA/0051/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 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)	13/07/2022	n/a		
WS/2219/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.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	07/07/2022	n/a		

IB/0049	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	29/04/2022	n/a		
II/0048/G	This was an application for a group of variations. B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	22/04/2022	n/a		
R/0047	Renewal of the marketing authorisation.	27/01/2022	04/03/2022		
WS/2182/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.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method 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.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS -	16/12/2021	n/a		

	Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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.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				
PSUSA/10501 /202105	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (live attenuated, nasal)	02/12/2021	n/a		PRAC Recommendation - maintenance
IA/0046	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	05/11/2021	n/a		
WS/2079/G	This was an application for a group of variations following a worksharing procedure according to	24/06/2021	n/a		

	Article 20 of Commission Regulation (EC) No 1234/2008. B.II.c.z - Change in control of excipients in the Finished Product - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation				
IB/0042	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	14/05/2021	04/03/2022	SmPC, Annex II, Labelling and PL	
IA/0043	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	07/05/2021	n/a		
R/0040	Renewal of the marketing authorisation.	28/01/2021	10/03/2021		
WS/1943/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.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant	14/01/2021	n/a		

	impact on the quality, safety or efficacy of the medicinal product				
WS/1942/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.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.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.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	14/01/2021	n/a		
PSUSA/10501 /202005	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (live attenuated, nasal)	14/01/2021	n/a		PRAC Recommendation - maintenance
IB/0036	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/10/2020	10/03/2021	SmPC and PL	
WS/1809/G	This was an application for a group of variations	09/07/2020	n/a		

	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.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS				
WS/1824	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.c.z - Change in control of excipients in the Finished Product - Other variation	25/06/2020	n/a		
IB/0032/G	This was an application for a group of variations. B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	25/03/2020	10/03/2021	SmPC, Annex II, Labelling and PL	
R/0031	Renewal of the marketing authorisation.	30/01/2020	16/03/2020		
WS/1739	This was an application for a variation following a worksharing procedure according to Article 20 of	12/12/2019	n/a		

	Commission Regulation (EC) No 1234/2008. B.I.z - Quality change - Active substance - Other variation				
PSUSA/10501 /201905	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (live attenuated, nasal)	28/11/2019	n/a		PRAC Recommendation - maintenance
IG/1142	A.7 - Administrative change - Deletion of manufacturing sites	11/09/2019	n/a		
IG/1143	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	26/08/2019	n/a		
WS/1646	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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	25/07/2019	n/a		
IG/1115/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	28/06/2019	n/a		

	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				
R/0019	Renewal of the marketing authorisation.	28/02/2019	17/04/2019		
IB/0023/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.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 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.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 -	28/03/2019	16/03/2020	Annex II and PL	

	Not including batch control/testing				
WS/1533	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.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	14/02/2019	n/a		
WS/1552	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.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	14/02/2019	n/a		
II/0020/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.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS -	14/02/2019	n/a		

	Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method 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.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.a.2.z - Changes in the manufacturing process 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.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.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.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) 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) 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.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 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.c.1.b - Change in immediate packaging of the AS - Qualitative and/or quantitative composition for sterile and non-frozen biological/immunological ASs B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including replacement or addition) B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol 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.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
PSUSA/10501 /201805	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (live attenuated, nasal)	29/11/2018	n/a		PRAC Recommendation - maintenance

WS/1499	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	22/11/2018	n/a		
II/0015	Update of section 4.6 of the SmPC with regard to pregnancy information based on cumulative review of pregnancy data from clinical trials, published literature and MAH pharmacovigilance database. The MAH took the opportunity to include editorial changes in section 4.8 and 5.1 of the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/07/2018	17/04/2019	SmPC	There are no data available on the use of Pandemic influenza vaccine H5N1 AstraZeneca in pregnant women. There is a moderate amount of data from the use of Fluenz Tetra in pregnant women, which is considered relevant to the Pandemic influenza vaccine. In more than 300 case reports in the MAH's safety database of vaccine administration to pregnant women, no unusual patterns of pregnancy complications or foetal outcomes were observed.
IG/0954	A.7 - Administrative change - Deletion of manufacturing sites	13/07/2018	n/a		
WS/1395	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	28/06/2018	n/a		
R/0011	Renewal of the marketing authorisation.	22/02/2018	04/04/2018		

IG/0907	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	26/03/2018	n/a		
IB/0012	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	01/03/2018	n/a		
II/0009/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 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	25/01/2018	n/a		
PSUSA/10501 /201705	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (live attenuated, nasal)	30/11/2017	n/a		PRAC Recommendation - maintenance
IA/0010/G	This was an application for a group of variations. 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	05/10/2017	n/a		

	finished product, including quality control sites (excluding manufacturer for batch release)				
IA/0008/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 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) 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)	20/09/2017	n/a		
T/0005	Transfer of Marketing Authorisation	27/05/2017	23/06/2017	SmPC, Labelling and PL	
PSUSA/10501 /201611	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (live attenuated, nasal)	09/06/2017	n/a		PRAC Recommendation - maintenance
IAIN/0006	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	24/05/2017	23/06/2017	SmPC, Labelling and PL	

R/0003	Renewal of the marketing authorisation.	23/02/2017	20/04/2017		
IB/0002/G	This was an application for a group of variations. B.II.d.1.b - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits for medicinal products subject to OCABR C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	14/01/2017	20/04/2017	SmPC	
IA/0001/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.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.c.3.z - Change in source of an excipient or reagent with TSE risk - Other variation	25/11/2016	n/a		