Amyvid

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
IA/0041	A.7 - Administrative change - Deletion of manufacturing sites	10/03/2021		Annex II, Labelling and PL	
IB/0040/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites	09/12/2020		SmPC, Annex II, Labelling and PL	

[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).

	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
IB/0039/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.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.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	12/10/2020	n/a		
IB/0038/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.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	12/08/2020	n/a		

	A.7 - Administrative change - Deletion of manufacturing sites B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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.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.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) 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.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)				
PSUSA/10032 /201904	Periodic Safety Update EU Single assessment - florbetapir (18f)	31/10/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10032 /201804	Periodic Safety Update EU Single assessment - florbetapir (18f)	31/10/2018	n/a		PRAC Recommendation - maintenance

IAIN/0036	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	12/07/2018	n/a		
IB/0034/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	04/06/2018	18/12/2018	Annex II and Labelling	
II/0029	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	17/05/2018	18/12/2018	SmPC	
IB/0033	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	24/04/2018	n/a		
IB/0032/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other	21/03/2018	n/a		

	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.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition 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.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol				
IB/0028/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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	11/01/2018	n/a		
IA/0031	A.7 - Administrative change - Deletion of manufacturing sites	21/12/2017	18/12/2018	Annex II and Labelling	
IA/0030	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)	21/12/2017	n/a		

PSUSA/10032 /201704	Periodic Safety Update EU Single assessment - florbetapir (18f)	26/10/2017	n/a		PRAC Recommendation - maintenance
R/0026	Renewal of the marketing authorisation.	20/07/2017	21/09/2017	SmPC, Labelling and PL	Based on the review of data on quality, safety, and efficacy, the CHMP considered that the benefit-risk balance of Amyvid in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0024/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	22/03/2017	21/09/2017	Annex II, Labelling and PL	
IA/0025	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	15/03/2017	n/a		
II/0022	Update of sections 4.4 and 5.1 of the SmPC in order to introduce quantitative read as an adjunct to visual	15/12/2016	06/02/2017	SmPC, Annex II and Labelling	Based on the data from studies QP01 and QP02, the MAH proposes changes to the SmPC, reflecting the following key

	read of florbetapir (18F) PET scans. In addition, the Marketing authorisation holder (MAH) took the opportunity bring the PI in line with the latest QRD template version 10.0. The updated RMP version 2.2 has been submitted C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				principles: • Addition of results and conclusions from studies QP01 and QP02 indicating that quantitation when used as an adjunct to the qualitative interpretation may improve readers' accuracy. • The use of quantitation is proposed to be optional because not all PET users may have access to software with quantitation capabilities suitable for use with the proposed method, and since the approved visual read method has been demonstrated to have sufficient accuracy. • The MAH proposes not to limit the use of quantitative software packages to those software packages used in the QP01 and QP02 trials. Indeed, the software packages used in these trials may not be available in all EU countries and new innovations in software packages may become available. Therefore, the proposed SmPC wording allows for broader quantitative software access and preserves the possibility of future innovations in the quantitative software. The quantitative reader training program will specify minimum recommended elements for quantitative software to be used as an adjunct quantitation of florbetapir (18F) PET images.
PSUSA/10032 /201604	Periodic Safety Update EU Single assessment - florbetapir (18f)	27/10/2016	n/a		PRAC Recommendation - maintenance
IB/0023/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a	21/10/2016	n/a		

	starting material/reagent/intermediate for AS - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation				
PSUSA/10032 /201510	Periodic Safety Update EU Single assessment - florbetapir (18f)	14/04/2016	n/a		PRAC Recommendation - maintenance
IG/0662	A.1 - Administrative change - Change in the name and/or address of the MAH	23/02/2016	06/02/2017	SmPC, Labelling and PL	
PSUSA/10032 /201504	Periodic Safety Update EU Single assessment - florbetapir (18f)	06/11/2015	n/a		PRAC Recommendation - maintenance
IAIN/0018/G	This was an application for a group of variations. 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.7 - Administrative change - Deletion of manufacturing sites	14/08/2015	10/12/2015	Annex II and Labelling	
N/0016	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/06/2015	10/12/2015	Labelling and PL	
IA/0015	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	20/05/2015	n/a		

	intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
IB/0014/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	05/05/2015	10/12/2015	Annex II, Labelling and PL	
PSUSA/10032 /201410	Periodic Safety Update EU Single assessment - florbetapir (18f)	10/04/2015	n/a		PRAC Recommendation - maintenance
IB/0012/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP -	22/12/2014	10/12/2015	SmPC, Annex II, Labelling and PL	

	Including batch control/testing				
IB/0010/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing 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	29/10/2014	n/a		
PSUV/0009	Periodic Safety Update	09/10/2014	n/a		PRAC Recommendation - maintenance
IA/0008	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	15/05/2014	n/a		
PSUV/0007	Periodic Safety Update	08/05/2014	n/a		PRAC Recommendation - maintenance
IB/0006/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the	18/10/2013	27/06/2014	Annex II, Labelling and PL	

	manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.b.2 - Change to batch release arrangements and quality control testing of the FP - Including batch control/testing				
IB/0005/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.b.2 - Change to batch release arrangements and quality control testing of the FP - Including batch control/testing	18/10/2013	27/06/2014	Annex II, Labelling and PL	
IB/0004/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are	18/10/2013	27/06/2014	Annex II, Labelling and PL	

	aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.b.2 - Change to batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place				
II/0002	Update of section 4.8 of the SmPC and section 4 of the PL to include injection site reactions. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	25/07/2013	27/06/2014	SmPC, Annex II, Labelling and PL	The undesirables' effects section of the SmPC and Package Leaflet has been updated to include the occurrence of injection site reaction (rash, bleeding or pain where the injection is given).
IG/0321	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/07/2013	n/a		
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/04/2013	27/06/2014	Labelling	