Letifend

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued / amended on	Product Information affected[2]	Summary[3]
IB/0027	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	18/02/2022		SPC and PL	The Agency accepted the variation to update section "4.6 Adverse reactions (frequency and seriousness)" of the SPC and section "6. Adverse reactions" of the PL to implement the wording agreed by the competent authority.
IA/0026	C.I.9.c - 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 PhV system	10/08/2021	n/a		n/a
IB/0025	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	04/06/2021		SPC and PL	The Agency accepted the variation to extend the shelf-life of the finished product as packaged for sale from 3 years to 4 years.
IAIN/0024/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.a - Administrative change - Change in the name and/or address of a manufacturer/importer	31/03/2021		SPC, Annex II, Labelling and PL	The Agency accepted the group of variations to change the name of the marketing authorisation holder and the name of the site responsible for batch release and secondary packaging. Additionally, the MAH took the opportunity to align the product information with the latest QRD template and correct some details in the list of local representatives.

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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	responsible for batch release A.1 - Administrative change - Change in the name and/or address of the MAH				
R/0023	Renewal of the marketing authorisation.	10/12/2020	09/02/2021	Annex II and PL	The European Commission renewed the marketing authorisation for Letifend.
IB/0019	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	28/05/2020	n/a		n/a
IB/0021	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	15/05/2020	n/a		n/a
IAIN/0022	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	08/05/2020	09/02/2021	PL	The Agency accepted the variation to update local representatives.
IB/0017	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	09/04/2020	n/a		n/a
IA/0020	C.I.9.c - 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 PhV system	30/03/2020	n/a		n/a
IB/0018	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	20/03/2020	n/a		n/a
IB/0016	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	21/02/2020	09/02/2021	SPC and PL	The Agency accepted the variation to update section 4.6 of the SPC and section 6 of the package leaflet to implement the changes requested following assessment of a PSUR.
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 intermediate used in the manufacture of the AS or manufacturer of a novel excipient	16/10/2019	n/a		n/a
IAIN/0014	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	03/04/2019	15/10/2019	PL	The Agency accepted the variation to amend the list of local representatives for Austria, Cyprus, Germany and Malta.
II/0012	B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	21/02/2019	n/a		The Agency accepted the variation to change the qualitative and quantitative composition of the immediate packaging of the finished product (solvent) from Ph. Eur. Type I coated glass vial to Ph. Eur. Type I standard glass vial for Letifend.
IA/0013	C.I.9.c - 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 PhV system	20/01/2019	n/a		The Agency accepted the variation to update the detailed description of pharmacovigilance (DDPS) from V2.0 to V3.0
IB/0011	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	04/10/2018	15/10/2019	SPC	The Agency accepted the variation to extend the shelf-life of the solvent as packaged for sale from 4 years to 5 years.
IAIN/0010	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	04/05/2018	n/a		The Agency accepted the variation to add an alternative site responsible for secondary packaging of the finished

	site				product
IB/0008	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	21/12/2017	n/a		The Agency accepted the variation to add a new vial sterilisation equipment - pre-fill.
IAIN/0009	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	24/11/2017	03/08/2018	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
IAIN/0007/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 and/or QPPV contact details and/or back-up procedure C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities	20/09/2017	n/a		The Agency accepted the variation to update the Detailed Description of the Pharmacovigilance System (DPPS), which includes the change of the QPPV back-up and pharmacovigilance contractual agreements.
IB/0006/G	This was an application for a group of variations. B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	18/08/2017	03/08/2018	SPC and Labelling	The Agency accepted the variation to increase the shelf life of the lyophilisate and the solvent.
IA/0005	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	16/05/2017	14/09/2017	SPC, Labelling and PL	The Agency accepted the variation to update the ATC Vet Code.
IA/0004	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	29/03/2017	n/a		The Agency accepted the variation to introduce a minor change to the sample processing for the residual humidity test method in order to better align the process with Ph.Eur. 2.5.32.
IB/0003	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	11/01/2017	n/a		The Agency accepted the variation to extend the shelf-life of the active substance to 3 years (36 months).
IB/0002	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	01/09/2016	14/09/2017	SPC	The Agency accepted the variation to extend the shelf-life of the solvent fraction from 2 years to 3 years.
IAIN/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	30/06/2016	n/a		The Agency accepted the variation to add an alternative site responsible for secondary packaging of the finished product.