EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Locatim

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]
II/0018	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	09/09/2021	n/a	SPC and PL	The Agency accepted the variation to replace the microagglutination method used for K99 antibody titration with an ELISA method.
IAIN/0022/G	This was an application for a group of variations. 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 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	11/08/2021	n/a		n/a
II/0021/G	This was an application for a group of variations. B.III.2.a.2 - Change of specification(s) of a former	15/07/2021	n/a		n/a

[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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	non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material B.III.2.c - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur. B.II.c.1.d - Change in the specification parameters and/or limits of an excipient - Change outside the approved specifications limits range B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation				
II/0017/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished	17/06/2021	n/a		n/a

	product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation 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.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.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.a.3.b.3 - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.z - Quality change - Finished product - Other variation				
IB/0020/G	This was an application for a group of variations. B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	26/05/2021	n/a		n/a
IB/0019/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes 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 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 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	21/05/2021		SPC, Labelling and PL	The Agency accepted the variation to add new pack sizes of 6, 12, 24 and 48 bottles.
IAIN/0016	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	09/12/2020	26/03/2021	Annex II and PL	The Agency accepted the variation to replace the registered batch release site. Additionally, the MAH has processed

	responsible for importation and/or batch release - Not including batch control/testing				minor QRD changes.
IAIN/0015	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	30/03/2020	26/03/2021	Annex II and PL	The Agency accepted the variation to change the name of the site responsible for batch release of the finished product and the site responsible for packaging of the finished product.
IB/0014	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	31/10/2019	n/a		n/a
IAIN/0013	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	25/09/2014	n/a		The Agency accepted the variation to change the qualified person responsible for pharmacovigilance (QPPV).
II/0012	B.II.a.3.b.3 - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product	13/06/2013	19/06/2014	SPC, Annex II, Labelling and PL	The Agency accepted the variation to remove propyl-parahydroxybenzoate from the formulation of Locatim.
IA/0010	1A-01 Change in name and/or address of MAH	09/01/2009	31/08/2009	SPC, Labelling and PL	The Agency accepted the variation to change the address of the marketing authorisation holder.
II/0011	II - Other quality changes	15/07/2009	24/07/2009		The European Commission amended the decision granting the marketing authorisation to remove the target animal batch safety test from the finished product testing.
R/0009	Renewal of the marketing authorisation.	15/10/2008	05/12/2008	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation.
R/0008	Renewal of the marketing authorisation.	10/02/2004	28/04/2004	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation.
IA/0007	1A-08-b-01 Change to batch release arrangements and quality control testing of the finished product	11/12/2003	n/a	Annex II, Labelling and PL	The Agency accepted the variation to change the address of the batch release site.
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/04/2003	08/05/2003	PL	The EMEA notified the European Commission of proposed changes to the contact details of the local representative for Germany. Amendments have been incorporated into the relevant section of the EPAR
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/03/2002	26/04/2002	Labelling and PL	The EMEA notified the European Commission of proposed changes to the contact details of the local representatives, linguistic changes to the product literature and an update to the package insert in accordance with the requirements of the codified Directive 2001/82/EC.
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/03/2000	25/04/2000	PL	The EMEA notified the European Commisison of proposed changes to the contact details of the local representatives.
I/0002	20_Extension of shelf-life as foreseen at time of authorisation	23/07/1999	29/10/1999	SPC	The EMEA accepted a type I variation extend the shelf life from 21 months to 30 months.

N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/08/1999	15/10/1999	PL	The EMEA notified the European Commission of proposed changes to the contact details of the local representatives.
I/0001	02_Change in the name of the medicinal product (either invented name of common name)	30/06/1999	14/09/1999	SPC, Labelling and PL	The EMEA accepted a type I variation to change the name of the product from "Serinucoli" to "Locatim".