



## Nemdatine

### Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
IB/0020/G	This was an application for a group of variations.  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	16/01/2024		SmPC, Annex II, Labelling and PL	

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



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.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site

B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site

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)

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

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B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation

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.1.z - Change in immediate packaging of the finished product - Other variation

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

	<p>responsible for importation and/or batch release - Not including batch control/testing</p> <p>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</p>				
IB/0018/G	<p>This was an application for a group of variations.</p> <p>B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>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</p> <p>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)</p>	30/10/2023	n/a		
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/08/2023		PL	
IAIN/0017/G	This was an application for a group of variations.	25/04/2023		SmPC, Annex	

	A.7 - Administrative change - Deletion of manufacturing sites A.1 - Administrative change - Change in the name and/or address of the MAH			II and PL	
IB/0016/G	This was an application for a group of variations.  B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	19/07/2022	n/a		
IB/0015	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	17/11/2021	22/03/2022	SmPC, Annex II, Labelling and PL	
IAIN/0014	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	29/03/2021	22/03/2022	Annex II and PL	
IA/0013	A.7 - Administrative change - Deletion of manufacturing sites	16/02/2021	22/03/2022	Annex II and PL	
IA/0012	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative	09/02/2021	n/a		

	composition - Solid pharmaceutical forms				
IB/0011/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.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	08/04/2020	n/a		
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/10/2018	22/03/2022	PL	
R/0008	Renewal of the marketing authorisation.	09/11/2017	08/01/2018	SmPC, Annex II, Labelling and PL	
IAIN/0009	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/10/2017	n/a		
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/06/2017	08/01/2018	Labelling and PL	
N/0006	Update of the labelling to add calendar days as an option for the starter pack blisters for all four strengths. And update of the package leaflet with revised contact details of the local representatives for Bulgaria, Belgium and Croatia. In addition, the MAH took the opportunity to make linguistic and editorial amendments to the Maltese, Hungarian,	06/07/2016	24/03/2017	Labelling and PL	

	<p>Czech, Spanish, French, German, Dutch, Swedish and Slovenian labelling and package leaflets.</p> <p>Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)</p>				
IB/0005/G	<p>This was an application for a group of variations.</p> <p>B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size</p> <p>B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation</p> <p>B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation</p> <p>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</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p> <p>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</p>	13/06/2016	n/a		

IAIN/0004	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	13/04/2016	24/03/2017	Annex II and PL	
IB/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/07/2015	13/04/2016	SmPC, Labelling and PL	
IAIN/0002/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.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	24/04/2015	13/04/2016	SmPC, Annex II, Labelling and PL	
IAIN/0001	B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	08/10/2013	11/11/2014	SmPC and PL	