



## Nustendi

### 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/0026	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	19/04/2022		PL	To update the local representatives in CZ and SL. In addition the MAH has taken to opportunity to correct an error in the ES SmPC.
IB/0025	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	11/03/2022	n/a		

<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).



PSUSA/10841 /202108	Periodic Safety Update EU Single assessment - bempedoic acid, bempedoic acid / ezetimibe	10/03/2022	n/a		PRAC Recommendation - maintenance
WS/2177/G	<p>This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>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</p> <p>B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier</p>	13/01/2022	n/a		
IB/0024/G	<p>This was an application for a group of variations.</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data</p> <p>B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data</p> <p>B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no</p>	10/01/2022	n/a		

	<p>further supportive data</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</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.a.2.z - Changes in the manufacturing process of the AS - Other variation</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>				
IB/0023	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	04/01/2022	n/a		
IB/0018	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/10/2021		SmPC	
PSUSA/10841 /202102	Periodic Safety Update EU Single assessment - bempedoic acid, bempedoic acid / ezetimibe	30/09/2021	n/a		PRAC Recommendation - maintenance
IB/0019/G	<p>This was an application for a group of variations.</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.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p>	25/08/2021	n/a		

	<p>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</p> <p>B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test</p> <p>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</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p>				
IB/0017	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	17/08/2021	n/a		
WS/2083/G	<p>This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.</p> <p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority</p> <p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission</p>	08/07/2021	n/a		

	<p>of studies to the competent authority</p> <p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority</p> <p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority</p> <p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority</p>				
IAIN/0016/G	<p>This was an application for a group of variations.</p> <p>B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data</p> <p>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)</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p>	02/06/2021	17/06/2021	Annex II and PL	
II/0007	<p>C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority</p>	15/04/2021	n/a		
PSUSA/10841 /202008	<p>Periodic Safety Update EU Single assessment - bempedoic acid, bempedoic acid / ezetimibe</p>	11/03/2021	n/a		PRAC Recommendation - maintenance
IB/0013	<p>B.II.f.1.b.1 - Stability of FP - Extension of the shelf life</p>	19/02/2021	17/06/2021	SmPC	

	of the finished product - As packaged for sale (supported by real time data)				
IB/0012	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	10/02/2021	n/a		
IB/0011/G	This was an application for a group of variations.  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 B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	06/01/2021	n/a		
IB/0010/G	This was an application for a group of variations.  C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation A.6 - Administrative change - Change in ATC Code/ATC Vet Code	10/12/2020	17/06/2021	SmPC, Annex II, Labelling and PL	
IA/0008/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.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	06/11/2020	n/a		

	control/testing takes place				
IB/0006/G	<p>This was an application for a group of variations.</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.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>	27/10/2020	n/a		
IB/0005/G	<p>This was an application for a group of variations.</p> <p>B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue</p> <p>B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue</p>	31/07/2020	n/a		
IAIN/0004/G	<p>This was an application for a group of variations.</p> <p>B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets,</p>	17/07/2020	17/06/2021	SmPC, Labelling and PL	

	<p>ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes</p> <p>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</p> <p>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</p> <p>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</p> <p>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</p>				
II/0002	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	09/07/2020	n/a		
IB/0003/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p>	05/06/2020	n/a		
T/0001	Transfer of Marketing Authorisation	07/05/2020	02/06/2020	SmPC,	



				Labelling and PL	
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