Nustendi

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
IB/0044/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.b.z - Change in control of the AS - Other	23/05/2024	n/a		

[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).

	variation				
IB/0043	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	22/05/2024	n/a		
II/0035	Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk for NUSTENDI, based on results from Study 1002-043, known as the CLEAR [Cholesterol Lowering via Bempedoic Acid, an ATP citrate lyase (ACL) Inhibiting Regimen] Outcomes Trial; this is a Phase 3, randomized, double-blind, placebo-controlled study to assess the effects of bempedoic acid (ETC-1002) on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease who are statin intolerant; As a consequence, sections 4.1, 4.4, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP has also been submitted. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	21/03/2024	10/05/2024	SmPC and PL	Please refer to Scientific Discussion 'Nustendi-H-C-004959-II-0035'
IA/0042	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	25/04/2024	n/a		

WS/2651	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	11/04/2024	n/a		
WS/2574	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.z - Change in control of the AS - Other variation	25/01/2024	n/a		
IAIN/0040/G	This was an application for a group of variations. B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data	24/01/2024	n/a		
IB/0039/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	10/01/2024	n/a		

	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.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size 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.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products				
IG/1671/G	This was an application for a group of variations. B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data 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	09/10/2023	n/a		

PSUSA/10841 /202302	Periodic Safety Update EU Single assessment - bempedoic acid, bempedoic acid / ezetimibe	28/09/2023	n/a		PRAC Recommendation - maintenance
WS/2562	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	21/09/2023	n/a		
IB/0033	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/04/2023	n/a		
PSUSA/10841 /202208	Periodic Safety Update EU Single assessment - bempedoic acid, bempedoic acid / ezetimibe	16/03/2023	n/a		PRAC Recommendation - maintenance
IA/0032	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	25/01/2023	n/a		
PSUSA/10841 /202202	Periodic Safety Update EU Single assessment - bempedoic acid, bempedoic acid / ezetimibe	29/09/2022	n/a		PRAC Recommendation - maintenance
IAIN/0030/G	This was an application for a group of variations. B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data	06/09/2022	n/a		

IA/0029	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	05/08/2022	n/a		
IB/0027	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	07/06/2022	n/a		
IB/0026	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	19/04/2022	14/10/2022	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		
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	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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 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	13/01/2022	n/a		

	not supported by an ASMF and requires significant update to the relevant AS section in the dossier				
IB/0024/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data 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.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	10/01/2022	n/a		
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	14/10/2022	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	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.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 control/testing takes place 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 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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	25/08/2021	n/a		

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	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	08/07/2021	n/a		
IAIN/0016/G	This was an application for a group of variations. B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the	02/06/2021	17/06/2021	Annex II and PL	

	finished product, including quality control sites (excluding manufacturer for batch release) A.7 - Administrative change - Deletion of manufacturing sites				
II/0007	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	15/04/2021	n/a		
PSUSA/10841 /202008	Periodic Safety Update EU Single assessment - bempedoic acid, bempedoic acid / ezetimibe	11/03/2021	n/a		PRAC Recommendation - maintenance
IB/0013	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)	19/02/2021	17/06/2021	SmPC	
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	10/12/2020	17/06/2021	SmPC, Annex II, Labelling	

	Veterinary Medicinal Products - Other variation A.6 - Administrative change - Change in ATC Code/ATC Vet Code			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 control/testing takes place	06/11/2020	n/a		
IB/0006/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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	27/10/2020	n/a		
IB/0005/G	This was an application for a group of variations. 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	31/07/2020	n/a		

	specification parameter as a result of a safety or quality issue 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				
IAIN/0004/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 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 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	17/07/2020	17/06/2021	SmPC, Labelling and PL	

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	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	05/06/2020	n/a		
T/0001	Transfer of Marketing Authorisation	07/05/2020	02/06/2020	SmPC, Labelling and PL	