Nilemdo

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
WS/2798	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	08/05/2025		SmPC and PL	As a result of this variation, sections 4.2, 4.4 and 5.2 of the SmPC are being updated including information on concerning renal impaired patients. The Package Leaflet (PL) has been updated accordingly. For more information, please refer to the Summary of Product Characteristics.

[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).

R/0042	Renewal of the marketing authorisation.	19/09/2024	18/11/2024	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Nilemdo in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0044	B.I.z - Quality change - Active substance - Other variation	30/10/2024	n/a		
PSUSA/10841 /202402	Periodic Safety Update EU Single assessment - bempedoic acid, bempedoic acid / ezetimibe	03/10/2024	n/a		PRAC Recommendation - maintenance
N/0043	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/09/2024	18/11/2024	PL	
IB/0040/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 variation	23/05/2024	n/a		
IB/0039	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/0031	Extension of indication to include treatment of adults with established or at high risk for atherosclerotic cardiovascular disease to reduce cardiovascular risk, based on results from study 1002-043 (CLEAR). CLEAR Outcomes Study is a phase 3 multi-centre	21/03/2024	10/05/2024	SmPC and PL	Please refer to Scientific Discussion 'Nilemdo-H-C-004958-II-0031'

	randomised, double-blind, placebo-controlled study to evaluate whether long-term treatment with bempedoic acid reduces the risk of major adverse cardiovascular events (MACE) in patients with, or at high risk for, cardiovascular disease who are statin intolerant. As a consequence, sections 4.1, 4.8 and 5.1 of the SmPC are updated. The Package Leaflet is updated accordingly. Version 5.0 of the RMP has also been submitted. In addition, the MAH took the opportunity to introduce minor formatting changes to the PI. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0037/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 B.II.z - Quality change - Finished product - Other variation	08/05/2024	n/a		
IA/0038/G	This was an application for a group of variations. 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 B.II.b.2.a - Change to importer, batch release	25/04/2024	n/a		

	arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
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/0035/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	23/01/2024	n/a		
IG/1671/G	This was an application for a group of variations.	09/10/2023	n/a		

	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 B.I.e.5.a - Implementation of changes foreseen in an approved change management protocol - Requires no further supportive data				
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		
PSUSA/10841 /202208	Periodic Safety Update EU Single assessment - bempedoic acid, bempedoic acid / ezetimibe	16/03/2023	n/a		PRAC Recommendation - maintenance
IB/0029	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	06/02/2023	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/0027/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/0026	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/0024	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/0023	To update the contact details of the local representatives in CZ and SK. In addition the MAH has taken the opportunity to align the ES SmPC section 4.1 to the approved EN annexes C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	01/04/2022	14/10/2022	PL	To update the contact details of the local representatives in CZ and SK. In addition the MAH has taken the oportunity to align the ES SmPC section 4.1 to the approved EN annexes
IB/0022	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 not supported by an ASMF and requires significant update to the relevant AS section in the dossier	13/01/2022	n/a		
IB/0021/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	11/01/2022	n/a		

	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				
IB/0020	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/0016	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/0017/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.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion	25/08/2021	n/a		

	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.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				
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	08/07/2021	n/a		

	elsewhere in this Annex which involve the submission of studies to the competent authority				
IAIN/0015/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.7 - Administrative change - Deletion of manufacturing sites	02/06/2021	05/07/2021	Annex II and PL	
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/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)	22/12/2020	05/07/2021	SmPC	
IA/0012/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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	17/12/2020	n/a		

IB/0010	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	11/12/2020	n/a		
IB/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/12/2020	05/07/2021	SmPC, Annex II, Labelling and PL	
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	22/10/2020	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 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	30/07/2020	n/a		

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	05/07/2021	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		
T/0001	Transfer of Marketing Authorisation	07/05/2020	12/06/2020	SmPC, Labelling and PL	

IB/0003	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	05/06/2020	n/a		