Pemetrexed Accord

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/0032	This was an application for a group of variations. B.III.1.a.5 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate of a non-sterile AS that is to be used in a sterile medicinal product, where water is used in the last	05/12/2024			

[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).

	steps of the synthesis and the material is not claimed to be endotoxin free 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				
PSUSA/2330/202402	Periodic Safety Update EU Single assessment - pemetrexed	17/10/2024	12/12/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2330/202402.
IAIN/0031/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	20/09/2024	12/12/2024	Annex II and PL	
II/0028	B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes	18/07/2024	n/a		
IB/0027/G	This was an application for a group of variations. 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	07/02/2024	n/a		

	batch control/testing takes place B.III.1.a.5 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate of a non-sterile AS that is to be used in a sterile medicinal product, where water is used in the last steps of the synthesis and the material is not claimed to be endotoxin free				
N/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/01/2024	09/10/2024	PL	
IA/0026/G	This was an application for a group of variations. 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) A.7 - Administrative change - Deletion of manufacturing sites 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	13/10/2023	09/10/2024	Annex II and PL	
II/0025	B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes	28/09/2023	n/a		
IA/0024/G	This was an application for a group of variations.	07/07/2023	n/a		

	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 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				
IA/0023	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)	17/02/2023	n/a		
II/0020	B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes	13/10/2022	n/a		
IA/0022	B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits	30/09/2022	n/a		
IB/0021	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	23/08/2022	03/02/2023	SmPC and PL	Sections 4.4 and 4.6 of the SmPC have been updated concerning duration of contraception following the end of treatment with a genotoxic drug, following assessment of the same changes adopted for the reference product. The package leaflet has been updated accordingly.

IB/0019	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	23/05/2022	n/a		
IA/0018	A.7 - Administrative change - Deletion of manufacturing sites	17/01/2022	03/02/2023	Annex II and PL	
PSUSA/2330/ 202102	Periodic Safety Update EU Single assessment - pemetrexed	30/09/2021	n/a		PRAC Recommendation - maintenance
IB/0017	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	29/07/2021	27/01/2022	PL	
IB/0015	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	04/06/2021	n/a		
IB/0014	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	07/01/2021	27/01/2022	SmPC and PL	
X/0010	Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form	17/09/2020	16/11/2020	SmPC, Labelling and PL	

R/0012	Renewal of the marketing authorisation.	23/07/2020	09/10/2020	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Pemetrexed Accord in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0013	B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	14/08/2020	n/a		
IB/0011	B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	06/05/2020	n/a		
IB/0009	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	28/05/2019	28/02/2020	SmPC and PL	
IA/0008	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	04/03/2019	n/a		
IAIN/0007/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	04/03/2019	28/02/2020	Annex II and PL	

	responsible for importation and/or batch release - Not including batch control/testing				
T/0006	Transfer of Marketing Authorisation	28/01/2019	25/02/2019	SmPC, Labelling and PL	
IB/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	20/04/2018	25/02/2019	SmPC and PL	
IB/0004	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	30/05/2017	07/06/2018	SmPC, Labelling and PL	
IA/0003	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)	14/09/2016	n/a		
IA/0002	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	03/08/2016	n/a		
IA/0001	B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	22/03/2016	n/a		