Pemetrexed Pfizer

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
N/0035	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/12/2024		PL	
IB/0034	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	07/10/2024	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).

	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				
IB/0033/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs 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	29/08/2022	04/08/2023	SmPC, Annex II, Labelling and PL	C.I.2.a - To update Sections 4.4 and 4.6 of the SmPC based on the recommended wording provided in the "Report from the CMD(h) meeting held on 20-21 July 2021" concerning duration of contraception following the end of treatment with a genotoxic drug. The PL has been updated accordingly.
IB/0030/G	This was an application for a group of variations. B.III.z - Quality Change - CEP/TSE/Monographs - Other variation B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits 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.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	01/07/2022	n/a		

	size 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.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation				
IB/0032	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	13/06/2022	n/a		
IB/0031/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.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS	12/05/2022	n/a		
N/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/03/2022	04/08/2023	PL	
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/09/2021	31/01/2022	PL	

IB/0027	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	08/04/2021	n/a		
IAIN/0026/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 A.7 - Administrative change - Deletion of manufacturing sites	08/02/2021	31/01/2022	Annex II and PL	
X/0021	Annex I_2.(c) Change or addition of a new strength/potency Annex I_2.(d) Change or addition of a new pharmaceutical form	23/07/2020	30/09/2020	SmPC, Labelling and PL	
IB/0025	C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	24/09/2020	n/a		
II/0024	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	24/09/2020	n/a		

	manufactured by complex manufacturing processes				
R/0022	Renewal of the marketing authorisation.	25/06/2020	10/08/2020	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 Hospira in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0023/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.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	24/06/2020	n/a		
II/0020/G	This was an application for a group of variations. B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF 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	16/01/2020	12/05/2020	Annex II and PL	
IB/0019	C.I.2.a - Change in the SPC, Labelling or PL of a	28/05/2019	12/05/2020	SmPC and PL	

	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				
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/04/2019	12/05/2020	PL	
IA/0017	A.7 - Administrative change - Deletion of manufacturing sites	18/03/2019	n/a		
IA/0016	A.7 - Administrative change - Deletion of manufacturing sites	19/12/2018	n/a		
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/10/2018	12/05/2020	PL	
T/0014	Transfer of Marketing Authorisation	06/08/2018	18/10/2018	SmPC, Labelling and PL	
IAIN/0013	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/04/2018	18/10/2018	SmPC and PL	
IA/0012	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)	28/02/2018	n/a		
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	20/11/2017	08/05/2018	PL	

IB/0010	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	15/09/2017	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	11/05/2017	08/05/2018	SmPC, Labelling and PL	
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/02/2017	08/05/2018	Labelling and PL	
IA/0007	A.7 - Administrative change - Deletion of manufacturing sites	03/02/2017	n/a		
IB/0006	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	14/01/2017	n/a		
IAIN/0005	C.I.11.a - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of wording agreed by the competent authority	08/07/2016	n/a		
N/0004	Update of the package leaflet with revised contact details of the local representatives for Belgium, Germany, Spain, Ireland, Luxembourg, the Netherlands, Austria and Portugal.	17/06/2016	08/05/2018	PL	

	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)				
IG/0693	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/06/2016	n/a		
IA/0002	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	25/02/2016	n/a		
IG/0645	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	17/12/2015	n/a		