EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pemetrexed Krka

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
R/0009	Renewal of the marketing authorisation	15/12/2022	15/02/2023	SmPC	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Pemetrexed Krka in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.

[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).

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IB/0008	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	24/08/2022	15/02/2023	SmPC and PL	
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/09/2021	18/11/2021	PL	
IAIN/0006/G	This was an application for a group of variations. B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	16/03/2021	n/a		
IB/0005	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	04/11/2020	18/11/2021	SmPC, Annex II, Labelling and PL	
IB/0004	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)	07/11/2019	04/05/2020	SmPC	
IB/0003	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure	17/05/2019	04/05/2020	SmPC and PL	

	concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation				
IA/0002	B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	05/10/2018	n/a		
IB/0001	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	08/08/2018	n/a		