Anagrelide Viatris

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
IG/1688	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	15/01/2024		SmPC, Labelling and PL	
PSUSA/208/202209	Periodic Safety Update EU Single assessment - anagrelide	12/05/2023	n/a		PRAC Recommendation - maintenance

[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/0013	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	28/04/2023	n/a		
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/02/2023		PL	
R/0010	Renewal of the marketing authorisation.	15/09/2022	21/11/2022	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Anagrelide Mylan in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. The PI is brought in line with with the SmPC guideline and the latest QRD template.
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	13/05/2022	20/10/2022	SmPC and PL	
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	13/10/2021	20/10/2022	SmPC	
T/0007	Transfer of Marketing Authorisation	12/08/2021	22/09/2021	SmPC, Labelling and	

				PL	
PSUSA/208/202009	Periodic Safety Update EU Single assessment - anagrelide	09/04/2021	n/a		PRAC Recommendation - maintenance
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	26/05/2020	09/07/2021	SmPC, Annex II, Labelling and PL	
PSUSA/208/201909	Periodic Safety Update EU Single assessment - anagrelide	17/04/2020	n/a		PRAC Recommendation - maintenance
PSUSA/208/201809	Periodic Safety Update EU Single assessment - anagrelide	11/04/2019	n/a		PRAC Recommendation - maintenance
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/03/2019	09/07/2021	PL	
IAIN/0001/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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	13/09/2018	n/a		