Jylamvo

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
IAIN/0023/G	This was an application for a group of variations. 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	21/10/2024		Annex II and PL	

[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).

	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 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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				
PSUSA/2014/202310	Periodic Safety Update EU Single assessment - methotrexate	27/06/2024	22/08/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2014/202310.
T/0022	Transfer of Marketing Authorisation	03/06/2024	05/07/2024	SmPC, Labelling and PL	
IB/0020	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	30/03/2023	16/02/2024	SmPC and PL	
IA/0019	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	25/01/2023	16/02/2024	SmPC	
PSUSA/2014/202110	Periodic Safety Update EU Single assessment - methotrexate	10/06/2022	n/a		PRAC Recommendation - maintenance
IB/0017	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/02/2022	21/11/2022	SmPC and PL	Update of Section 4.4 of the SmPC and of the PL by adding revised wording on liver function tests.

IAIN/0016	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/11/2021	21/11/2022	SmPC and PL	
R/0015	Renewal of the marketing authorisation.	16/09/2021	22/11/2021		Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Jylamvo in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IAIN/0014	A.1 - Administrative change - Change in the name and/or address of the MAH	14/04/2021	22/11/2021	SmPC, Labelling and PL	
IAIN/0013/G	This was an application for a group of variations. 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 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 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	15/01/2021	22/11/2021	Annex II and PL	
IB/0012	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)	04/01/2021	22/11/2021	SmPC	

PSUSA/2014/201910	Periodic Safety Update EU Single assessment - methotrexate	28/05/2020	10/08/2020	SmPC and PL	Please refer to Jylamvo - Nordimet EMEA/H/C/PSUSA/00002014/201910 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation.
IA/0010	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	20/12/2019	n/a		
A31/0002	Pursuant to Article 31 of Directive 2001/83/EC, Spain requested on 22 March 2018 the opinion of the European Medicines Agency further to serious cases of overdose, sometimes fatal, having been reported in patients inadvertently receiving the product daily instead of weekly for indications that require weekly dosing despite additional risk minimisation measures having been put in place by several Member States. The CHMP was requested to assess the impact thereof on the benefit-risk balance of methotrexate-containing medicinal products and to give its recommendation whether the marketing authorisation of these products should be maintained, varied, suspended or revoked. As the request results from the evaluation of data resulting from pharmacovigilance activities, the CHMP opinion should be adopted on the basis of a recommendation of the Pharmacovigilance Risk Assessment Committee (PRAC).	22/08/2019	21/10/2019	SmPC, Annex II and Labelling	Please refer to the assessment report: Jylamvo EMEA/H/A-31/1463/C/3756/0002 Nordimet EMEA/H/A-31/1463/C/3983/0006

IAIN/0008/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 responsible for importation and/or batch release - Not including batch control/testing B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	05/09/2019	10/08/2020	Annex II and PL	
PSUSA/2014/ 201810	Periodic Safety Update EU Single assessment - methotrexate	27/06/2019	26/08/2019	SmPC and PL	Please refer to Jylamvo - Nordimet EMEA/H/C/PSUSA/00002014/201810 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
II/0005/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	25/07/2019	21/10/2019	SmPC	

T/0007	Transfer of Marketing Authorisation	15/03/2019	29/03/2019	SmPC, Labelling and PL	
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/01/2019	28/03/2019	Labelling	
PSUSA/2014/ 201706	Periodic Safety Update EU Single assessment - methotrexate	22/03/2018	22/05/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2014/201706.
IAIN/0003	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/04/2018	28/03/2019	SmPC and PL	