EMA/298797/2020

Jorveza

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
X/0007/G	This was an application for a group of variations. - Extension of application to include a new strength 0.5 mf orodispersible tablet - Extension of indication to include the maintenance of remission for Jorveza (0.5 mg and 1 mg	26/03/2020	20/05/2020	SmPC, Labelling and PL	Please refer to the scientific discussion: Jorveza EMEA/H/C/004655/X/0007/G

[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).

	orodispersible tablets); as a consequence, sections 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated to reflect the recommended daily dose and duration of treatment of Jorveza for the maintenance of remission, to update the list of adverse reactions and the clinical efficacy and safety information based on the results of the phase III clinical study BUL-2/EER. The relevant sections of the package leaflet are updated accordingly. In addition, a revised RMP (version 2.1) has been submitted to reflect the results of this study and to align with the GVP Module V (rev 2) template. The MAH also took the opportunity to bring the product information in line with the latest QRD template (version 10.1). - To add a new pack-size of 200 x 1 orodispersible tablets (unit dose) in a blister for Jorveza 1 mg orodispersible tablet (EU/1/17/1254/006) Annex I_2.(c) Change or addition of a new strength/potency B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
PSUSA/10664 /201907	Periodic Safety Update EU Single assessment - budesonide (centrally authorised products only)	16/01/2020	n/a		PRAC Recommendation - maintenance

PSUSA/10664 /201901	Periodic Safety Update EU Single assessment - budesonide (centrally authorised products only)	11/07/2019	n/a		PRAC Recommendation - maintenance
IA/0006	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	14/06/2019	n/a		
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/05/2019	20/05/2020	PL	
IA/0004	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)	29/04/2019	n/a		
IB/0002	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	29/01/2019	n/a		
PSUSA/10664 /201807	Periodic Safety Update EU Single assessment - budesonide (centrally authorised products only)	17/01/2019	n/a		PRAC Recommendation - maintenance