EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Staquis

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/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/10/2021		PL	
PSUSA/10842 /202012	Periodic Safety Update EU Single assessment - crisaborole	08/07/2021	n/a		PRAC Recommendation - maintenance
IAIN/0004/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition	01/03/2021		SmPC, Annex II, Labelling 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).

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	of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
PSUSA/10842 /202006	Periodic Safety Update EU Single assessment - crisaborole	14/01/2021	n/a		PRAC Recommendation - maintenance
IB/0001	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/07/2020	n/a		