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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
WS/2405	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	25/05/2023		SmPC, 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).

	data				
PSUSA/2266/202106	Periodic Safety Update EU Single assessment - paliperidone	10/02/2022	n/a		PRAC Recommendation - maintenance
X/0002/G	This was an application for a group of variations. Annex I_2.(c) Change or addition of a new strength/potency A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength A.7 - Administrative change - Deletion of manufacturing sites	16/09/2021	22/11/2021	SmPC, Labelling and PL	
WS/1877	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/04/2021	22/11/2021	SmPC and PL	