Zycortal

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued / amended on	Product Information affected[2]	Summary[3]
R/0007	Renewal of the marketing authorisation.	18/06/2020	20/08/2020	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Zycortal.
IAIN/0006/G	This was an application for a group of variations. 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.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	09/04/2019	18/02/2020	Annex II and PL	The Agency accepted the group of variations to introduce an additional manufacturer responsible for batch release and an importation site.
IB/0005	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	22/02/2019	18/02/2020	SPC and PL	The Agency accepted the variation to update the SPC and package leaflet following assessment of a PSUR.
II/0003	C.II.7.a - Introduction of a new Pharmacovigilance system - Which has not been assessed by the relevant national competent authority/EMA for another product	21/02/2019	n/a		The Agency accepted the variation to introduce a new pharmacovigilance system.

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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	of the same MAH				
T/0002	Transfer of Marketing Authorisation	29/10/2018	04/02/2019	SPC, Annex II, Labelling and PL	The European Commission transferred the marketing authorisation from 'Dechra Ltd' to 'Dechra Regulatory B.V.'
IA/0004	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	15/01/2019	n/a		The Agency accepted the variation to replace a site where batch control/testing takes place.
IA/0001	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	13/10/2017	n/a		The Agency accepted the variation to add a new site where batch control/testing takes place.