LEDAGA

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
T/0008	Transfer of Marketing Authorisation	22/11/2018	18/12/2018	SmPC, Labelling and PL	
PSUSA/10587 /201802	Periodic Safety Update EU Single assessment - chlormethine	06/09/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10587 /201708	Periodic Safety Update EU Single assessment - chlormethine	08/03/2018	n/a		PRAC Recommendation - maintenance

[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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IG/0839	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	20/11/2017	28/05/2018	SmPC, Annex II and PL	
IB/0003/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.II.z - Quality change - Finished product - Other variation	15/09/2017	n/a		
IA/0001	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	28/06/2017	28/05/2018	SmPC and PL	