Cepedex

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
IB/0003/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	19/09/2018		SPC	The Agency accepted the variation to extend the shelf-life of the finished product from 2 to 3 years and to tighten the shelf-life specification.
IAIN/0002	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	04/05/2017	04/06/2018	PL	The Agency accepted the variation to update the holder's representative information in the Package Leaflet.
IAIN/0001	C.II.8 - Change in the frequency and/or date of submission of PSURs	18/04/2017	n/a		The European Medicines Agency accepted the variation to synchronise the PSUR submission for Cepedex with the reference product Dexdomitor.

[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] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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