EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Cepedex

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.	09/09/2021	11/11/2021	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Cepedex.
IB/0005	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	14/11/2019	20/11/2020	SPC	The Agency accepted the variation to extend the shelf life of the finished product from 36 to 48 months.
IG/1050	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	18/01/2019	n/a		The Agency accepted the variation to change the qualified person for pharmacovigilance (QPPV).
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	20/09/2019	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	04/05/2017	04/06/2018	PL	The Agency accepted the variation to update the holder's

[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

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	information concerning the holder's representative				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.