Kexxtone

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
IAIN/0011	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	19/12/2018		Annex II and PL	The Agency accepted the variation to add a new manufacturer responsible for importation and batch release.
IG/1040/G	This was an application for a group of variations. 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 C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	17/12/2018	n/a		The Agency accepted the group of variations to update the detailed description of the pharmacovigilance system (DDPS).
T/0010	Transfer of Marketing Authorisation	25/07/2018	24/09/2018	SPC, Labelling	The European Commission transferred the marketing

[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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				and PL	authorisation from 'Elanco Europe Ltd' to 'Elanco GmbH'.
R/0009	Renewal of the marketing authorisation.	05/10/2017	06/12/2017	SPC, Annex II, Labelling and PL	The European Commission renewed the Marketing Authorisation for Kexxtone.
IB/0008	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	15/04/2016	05/05/2017	SPC, Labelling and PL	The Agency accepted the variation to update sections 4.5 and 4.6 of the SPC to update the safety information. The package leaflet and labelling are updated accordingly.
IAIN/0007	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	13/02/2015	n/a		The Agency accepted the variation on the addition of an alternative secondary packaging site for Kexxtone.
IB/0006/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	05/11/2014	n/a		The Agency accepted a group of variations for a minor change to the production of tablet cores and a change to loss on drying limit for granule sub-lots as a consequence of validation results during scale-up.
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)	24/10/2014	10/06/2015	SPC	The Agency accepted the variation to extend the current shelf-life of the product as packaged for sale from 24 to 36 months based on the results of the real time stability study.
IG/0437	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	28/05/2014	10/06/2015	PL	The Agency accepted the variation to update the product information with the Croatian translation.
IG/0364/G	This was an application for a group of variations. 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 C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	31/10/2013	n/a		The Agency accepted the variation to change the QPPV and to update the DDPS.
IB/0002	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	05/08/2013	n/a		The Agency accepted a variation for a change in the manufacturing process
IB/0001/G	This was an application for a group of variations. B.II.a.2.b - Change in the shape or dimensions of the pharmaceutical form - Gastro-resistant, modified or prolonged release pharmaceutical forms and scored tablets intended to be divided into equal doses B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure	21/05/2013	n/a		The Agency accepted a group of variations concerning quality changes.