EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Recuvyra

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion / Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IB/0009/G	This was an application for a group of variations. C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR 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.	13/02/2015		SPC and PL	The Agency accepted a variation to amend sections 4.5 and 4.6 of the SPC and section 6 of the package leaflet following PSUR assessment and to update details of representatives within the package leaflet.
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		PL	The Agency accepted the variation on updating product Information with Croatian translation.

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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No	Scope	Opinion / Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
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 IG variation to change the QPPV and to update the DDPS with administrative changes with regard to the presentation of the system.
IG/0237	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV	29/11/2012	n/a		The European Medicines Agency accepted a variation to change the QPPV (Qualified person for Pharmacovigilance) for Eli Lilly products.
T/0005	Transfer of Marketing Authorisation	16/02/2012	15/03/2012	SPC, Labelling, PL	The European Commission amended the decision granting the marketing authorisation to transfer the marketing authorisation from 'Nexcyon Pharmaceuticals Ltd' to 'Eli Lilly and Company Ltd'.
IAIN/0004	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	21/12/2011	15/03/2012	Annex II, Labelling	The European Medicines Agency accepted a type IAIN variation regarding a change to batch release arrangements.
IA/0003	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	21/12/2011	n/a		The European Medicines Agency accepted a type IA variation to change the batch size of the finished product.

No	Scope	Opinion / Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IAIN/0002	B.III.1.a.3 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	14/12/2011	n/a		The European Medicines Agency accepted a type IAIN variation regarding a change to the manufacturer of the active substance.
IAIN/0001	C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD	12/12/2011	n/a		The European Medicines Agency accepted a type IAIN variation relating to changes to the detailed description of the pharmacovigilance system (DDPS).