EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Meloxivet

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
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.
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.

[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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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.
R/0008	Renewal of the marketing authorisation	13/09/2012	08/11/2012	SPC, Labelling, PL	The European Commission renewed the marketing authorisation for Meloxivet.
IB/0009	C.I.8.b - Introduction of a new Pharmacovigilance system - which has been assessed by the relevant NCA/EMA for another product of the same MAH	15/06/2012	n/a		The European Medicines Agency accepted a type IB variation to add a new DDPS as a result of the transfer of the marketing authorisation from 'Janssen Pharmaceutica NV' to 'Eli Lilly & Company Ltd'.
T/0007	Transfer of Marketing Authorisation	20/03/2012	20/04/2012	SPC, Labelling, PL	The European Commission amended the decision granting the marketing authorisation to transfer the marketing authorisation from 'Janssen Pharmaceutica N.V.' to 'Eli Lilly and Company Ltd'.
IG/0004/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	03/05/2011	03/05/2011		The European Medicines Agency accepted a group of type IA variations to change the Qualified Person for Pharmacovigilance
IB/0005	1B-43-b Addition, replacement or deletion of a measuring or administration device	12/11/2009	15/03/2010	SPC, Labelling, PL	The EMEA accepted a variation to register a second syringe for Meloxivet 1.5 mg/ml for the 10 ml presentation.
IB/0002	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	12/12/2008	14/07/2009	SPC	The EMEA accepted a variation to extend the shelf-life of Meloxivet 0.5mg/ml oral suspension and Meloxivet 1.5mg/ml oral suspension from 24 to 36 months.

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IA/0004	1A-32.b Change in the batch size of the finished product-Downscaling down to 10-fold	06/07/2009	06/07/2009		The EMEA accepted a variation to introduce an additional batch size of 300 L for Meloxivet 0.5 mg/ml oral suspension only, in addition to the current 500 L and 3,000 L batch size. The batch size of Meloxivet 1.5 mg/ml oral suspension remains unchanged.
IA/0003	1A-25-b-2 Change to comply with Eu. Ph. or with the national pharmacopoeia of a Member State	18/11/2008	18/11/2008		The EMEA accepted a variation concerning a change to comply with an update of the relevant monograph of the European Pharmacopoeia regarding the excipients microcrystalline cellulose and camellose sodium.
II/0001	Change to detailed description of pharmacovigilance system	15/10/2008	20/10/2008		The European Commission amended the decision granting the marketing authorisation to change the qualified person responsible for pharmacovigilance.