Emdocam

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]
IAIN/0016	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	28/05/2021		PL	The Agency accepted the variation to update the list of local representatives.
X/0013	Annex I_2.(d) Change or addition of a new pharmaceutical form	17/02/2021	26/04/2021	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include a new strength, dosage form and route of administration.
X/0012	Annex I_2.(c) Change or addition of a new strength/potency	17/02/2021	26/04/2021	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include a new strength and two new target species.
IB/0015	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	09/10/2020	n/a		n/a
IG/1202	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	20/02/2020	09/02/2021	PL	The Agency accepted the group of variations to amend the contact details of the United Kingdom and Cyprus local representatives in the package leaflet.
IAIN/0011	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	11/02/2019	18/02/2020	PL	The Agency accepted the variation to change the local representatives in Ireland and Slovenia and to align the product information with the latest version of the QRD

[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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IB/0010	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	17/11/2017	n/a		The Agency accepted the variation to introduce minor changes to the starting products.
IA/0009	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	01/07/2016	n/a		The Agency accepted the variation to update the Ph. Eur. Certificate of Suitability for meloxicam.
R/0007	Renewal of the marketing authorisation.	21/04/2016	21/06/2016	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Emdocam.
IAIN/0008/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	19/04/2016	n/a		The Agency accepted the group of variations to update the Detailed Description of the Pharmacovigilance System (DDPS) to include a change in the Qualified Person for Pharmacovigilance (QPPV) and to include administrative changes not impacting the operation of the pharmacovigilance system.
IB/0006	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	10/12/2014	30/01/2015	SPC and PL	The Agency accepted the variation to bring the SPC and package leaflet into agreement with that of the reference product.
IAIN/0005	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	11/04/2014	30/01/2015	PL	The Agency accepted the variation to make changes to the list of local representatives.
IB/0004	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	26/03/2013	03/12/2013	PL	The Agency accepted the variation to change local representatives on the package leaflet.
IB/0003/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	20/12/2012	03/12/2013	SPC and PL	The Agency accepted the variation to amend the adverse reactions section of the SPC to be in line with the reference product and to amend the local representatives in the package leaflet.
IB/0001	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	18/11/2011	14/06/2012	PL	The Agency accepted the variation to add local representatives to the package leaflet.
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	22/12/2011	n/a		The Agency accepted the variation for a change in a test procedure.