Acticam

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/0023	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	24/04/2020		PL	The Agency accepted the variation to update the list of local representatives in the Package Leaflet. The Product Information was aligned with QRD template v8.1.
IB/0022	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	10/10/2019	n/a		n/a
IAIN/0021/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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 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	10/09/2019	n/a		n/a

[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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IAIN/0019	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	26/02/2019	08/04/2020	PL	The Agency accepted the variation to add contact details of the local representatives to the package leaflet.
IAIN/0018	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	07/09/2018	n/a		The Agency accepted the variation to change the QPPV.
IAIN/0017	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	16/12/2016	n/a		The Agency accepted the variation to update the Detailed Description of the Pharmacovigilance System (DDPS).
IA/0016/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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	19/10/2016	n/a		The Agency accepted the variation to introduce minor changes in the manufacturing process of the finished product.
IA/0015/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	20/02/2015	n/a		The Agency accepted the variation to add 2 new testing sites.
II/0014	B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	15/01/2015	n/a		The Agency accepted the variation for a change in immediate packaging of the finished product.
R/0013	Renewal of the marketing authorisation.	10/10/2013	09/12/2013	SPC and PL	The European Commission renewed the marketing authorisation for Acticam.
IA/0012	B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	15/02/2013	n/a		The Agency accepted the variation relating to an updated Ph. Eur. certificate of suitability for an active substance.
IAIN/0011/G	This was an application for a group of variations. B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information	27/07/2012	10/10/2012	SPC	The Agency accepted the group of variations to change a test in line with the Ph. Eur. and to change the flip-off seal.

IAIN/0010/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV	04/04/2012	10/10/2012	Annex II and PL	The Agency accepted the group of variations to amend a typographical error in the address of the batch release manufacturer and to change the Qualified Person for Pharmacovigilance.
IAIN/0009	B.III.1.a.1 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	16/12/2010	16/12/2010		The Agency accepted the variation to add a new certificate of suitability of the active substance Meloxicam. The manufacturer of the active substance remains the same.
ART45/0008		15/09/2010	15/09/2010		The European Commission requested on 19 August 2010, in the interests of animal health, the opinion of the CVMP on the measures necessary to ensure the quality of Acticam 1.5 mg/ml oral suspension for dogs.
IA/0007	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	27/05/2010	01/09/2010	SPC, Annex II, Labelling and PL	The Agency accepted the variation to change the manufacturer responsible for batch release.
IB/0004	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)	20/07/2010	01/09/2010	SPC, Annex II, Labelling and PL	The Agency accepted the variation to change the shelf-life of the finished product from 2 to 3 years.
IA/0006	B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place	27/05/2010	27/05/2010		The Agency accepted the variation to add a new manufacturer responsible for batch control/testing.
IA/0005	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	27/05/2010	27/05/2010		The Agency accepted the variation to add a new site for secondary packaging for Acticam solution for injection and Acticam oral suspension.
T/0003	Transfer of Marketing Authorisation	21/01/2010	30/03/2010	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from "Omnipharm" to "Ecuphar NV".
IA/0002	1A-01 Change in name and/or address of MAH	27/10/2009	27/10/2009	SPC, Labelling and PL	The Agency accepted the variation to change the address of the marketing authorisation holder.