Oncept IL-2

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]
IG/1279	A.7 - Administrative change - Deletion of manufacturing sites	14/08/2020	n/a		n/a
IG/1264	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	29/07/2020		Annex II	The Agency accepted the variation to change the name of a site responsible for the manufacture of the active substance.
IG/1230	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	08/04/2020	n/a		n/a
IG/1204/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/importer responsible for batch release A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	20/03/2020		Annex II and PL	The Agency accepted the group of variations to change the names of the site responsible for batch release of the finished product and the site responsible for packaging of the finished product.

[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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T/0010	Transfer of Marketing Authorisation	29/11/2019	17/12/2019	SPC, Labelling and PL	The European Commission transferred the marketing authorisation for Oncept IL-2 from 'MERIAL' to 'Boehringer Ingelheim Vetmedica GmbH'.
IG/1127/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	10/07/2019	n/a		n/a
WS/1366	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	19/04/2018	n/a		n/a
R/0006	Renewal of the marketing authorisation.	18/01/2018	20/03/2018	SPC, Annex II, Labelling and PL	The European Commision renewed the marketing authorisation for Oncept IL-2.
IA/0007	B.III.1.a.4 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material)	22/02/2018	n/a		The Agency accepted the variation to delete the corresponding Ph.Eur. Certificate of suitability for a supplier of calf serum.
WS/1195	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol	15/02/2018	n/a		n/a
WS/1095	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	15/06/2017	n/a		n/a

	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation				
IA/0003	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	23/05/2016	n/a		The Agency accepted the variation to delete an obsolete specification parameter, Target Animal Batch Safety Test (TABST), from the specifications of the finished product.
IG/0592	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	04/09/2015	n/a		n/a
IB/0001	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	24/04/2015	20/04/2016	SPC	The Agency accepted the variation to extend the shelf-life of the finished product from 18-months to 24 months.