Halocur

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IB/0016	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	16/08/2019		SPC, Annex II, Labelling and PL	The Agency accepted the variation to correct some deficiencies in the Estonian PI and update all the translations according to the latest QRD template (version 8.1).
IB/0015/G	This was an application for a group of variations. B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	12/08/2016	n/a		The Agency accepted the group of variations to add an alternative site responsible for manufacture of the active substance, to increase the batch size of the active substance and to add a new specification parameter to the specifications of the active substance.

[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] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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IB/0014	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	13/11/2015	n/a		The Agency accepted the variation to extend the re-test period of the active substance, halofuginone lactate, based on real time stability data.
IB/0013	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	26/02/2015	n/a		The Agency accepted the variation to reduce the testing frequency for the in-process control for the filling volume.
IB/0012	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	04/08/2014	n/a		The Agency accepted the variation to change a specification limit of a parameter of the finished product.
IB/0011	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	07/12/2012	n/a		The Agency accepted the variation to change the in-process control limits of Halocur.
IB/0010	B.II.d.2.z - Change in test procedure for the finished product - Other variation	21/09/2012	n/a		The Agency accepted the variation to amend a test procedure.
II/0009	B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is supported by an ASMF	13/10/2010	03/11/2010		The European Commission amended the decision granting the marketing authorisation to introduce a new manufacturer of an intermediate product used in the manufacturing process of the active substance.
IB/0007	1B-17-a Change in the re-test period of the active substance	18/12/2009	18/12/2009		The Agency accepted the variation to change the re-test period of the active substance halofuginone lactate.
IB/0008	1B-33 Minor change in the manufacture of the finished product	16/12/2009	16/12/2009		The Agency accepted the variation concerning a minor change in the manufacture of the finished product.
R/0006	Renewal of the marketing authorisation.	16/09/2009	23/11/2009		The European Commission approved an indefinite renewal of the marketing authorisation.
IB/0005	1B-32-c Change in the batch size of the finished product-Other situations	11/06/2008	11/06/2008		The Agency accepted the variation to change the batch size.
II/0004	II - Other quality changes	13/06/2007	18/06/2007		The European Commission amended the decision granting the marketing authorisation regarding a change in the manufacturer for the active substance.
R/0003	Renewal of the marketing authorisation.	07/09/2004	25/11/2004	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Halocur.
I/0002	01_Change following modification(s) of the manufacturing authorisation(s)	27/09/2002	24/10/2002	Annex II, Labelling and PL	The EMEA accepted a type I variation to change the name of the manufacturer of the medicinal product from "Hoechst Roussel Vet" to "Intervet Production S.A" while the manufacturing site shall remain the same. The general conditions to the Marketing Authorisation and the labelling texts were amended accordingly.
T/0001	Transfer of Marketing Authorisation	21/11/2000	28/12/2000	SPC, Labelling and PL	The European Commission approved a transfer of the marketing authorisation to from "Hoechst Roussel Vet" to "Intervet International BV".