Meloxidolor

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]
IB/0011	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)	22/12/2020		SPC	The Agency accepted the variation to extend the shelf life of the finished product from 24 months to 36 months.
IG/1170	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	19/12/2019	n/a		n/a
IG/1168	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	12/11/2019	30/10/2020	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
WS/1666	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.II.7.b - Introduction of a new Pharmacovigilance system - Which has been assessed by the relevant national competent authority/EMA for another product of the same MAH	10/10/2019	n/a		The Agency accepted the variation to update the current detailed description of the pharmacovigilance system (DDPS).
R/0007	Renewal of the marketing authorisation.	15/03/2018	20/04/2018		The European Commission renewed the marketing

[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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					authorisation for Meloxidolor.
IAIN/0006	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	05/02/2016	04/04/2016	PL	The Agency accepted the variation to update the list of local representatives in the leaflet.
IB/0005/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	17/07/2015	04/04/2016	SPC, Labelling and PL	The Agency accepted the variation to add three new multipack presentations.
IB/0004	C.I.7.b - Deletion of - a strength	03/07/2015	04/04/2016	SPC, Labelling and PL	The Agency accepted the variation to delete the strength 40 mg/ml solution for injection.
IAIN/0003	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	31/03/2015	04/04/2016	PL	The Agency accepted the variation to update the list of local representatives in the leaflet.
IAIN/0002	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	20/12/2013	n/a		The Agency accepted the variation for a submission of a new certificate from a new manufacturer for an active substance.
IB/0001	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	25/10/2013	03/12/2013	SPC, Labelling and PL	The Agency accepted the variation of adjusting the indication for cattle to the registered range of Meloxidolor solution for the following presentations 5 mg/ml, 20 mg/ml and 40 mg/ml. The approved indication is: For the relief of post-operative pain following dehorning in calves.