Dexdomitor

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
IAIN/0037	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	03/05/2018		PL	The Agency accepted the variation to make changes within the list of the local representatives in the package leaflet.
IAIN/0036	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	18/10/2017		PL	The Agency accepted the variation to update the list of the local representatives in the package leaflet. Additionally, the manufacturers of the active substance, which were erroneously included in Annex II, were deleted.
IA/0035	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	14/03/2017	n/a		The Agency accepted the variation to change a testing method for Dexdomitor 0.5 mg/ml solution for injection.
IB/0034/G	This was an application for a group of variations. B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a	17/06/2016	n/a		The Agency accepted the variation to update the ASMF for dexmedetomidine hydrochloride.

[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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

	test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS 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 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 B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation				
IAIN/0033	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	15/03/2016	29/03/2017	SPC, Annex II, Labelling and PL	The Agency approved the variation to update the list of local representatives in the package leaflet.
IAIN/0032	C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	24/04/2015	n/a		The Agency accepted the variation to update the DDPS.
IB/0031	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	19/12/2014	05/03/2015	SPC, Labelling and PL	The Agency accepted the variation to extend the shelf-life after first opening from 28 days to 3 months.
IAIN/0030	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	07/11/2014	05/03/2015	PL	The Agency accepted the variation on updating the distributors listed in the package leaflet.
IAIN/0029/G	This was an application for a group of variations. 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 C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	23/05/2014	n/a		The Agency accepted the variation on changing the Detailed Description of the Pharmacovigilance System (DDPS).
IAIN/0028	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	14/03/2014	05/03/2015	Labelling and PL	The Agency accepted the variation on adding new administrative information and incorporating Croatian product information.

IA/0027	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	28/02/2014	n/a		The Agency accepted a variation on addition of the alternative functional secondary packaging material. The name of the manufacturer from the secondary packaging material has been removed.
IA/0026/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/12/2013	n/a		The Agency accepted a grouped variation on changing the specification limits and test procedure for active substance.
IA/0025	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	11/09/2013	n/a		The Agency accepted a variation on changing the electronic reporting system in the DDPS.
IB/0023	B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	21/06/2013	n/a		The Agency accepted a variation on the change of the batch size of 580 litres.
IB/0022	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	21/06/2013	n/a		The Agency accepted the variation on a change in the manufacturing process of the finished product.
IA/0024	B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised	14/06/2013	n/a		The Agency accepted the variation on deletion of an alternative test method.
IB/0021	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	20/12/2012	n/a		The Agency accepted the variation on changing the in-process limits.
IB/0020	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	04/10/2012	25/10/2012	PL	The Agency accepted the variation on amending the package leaflet.
X/0019	X-3-III Extension to a new strength	14/06/2012	30/08/2012	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include a new strength for Dexdomitor 0.1 mg/ml solution for injection for dogs and cats.
II/0018	II - New Indication (same therapeutic area)	14/10/2009	18/11/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new indication for premedication in cats and reduction of the age in the warning not to use Dexdomitor in puppies to below 16 weeks of age and kittens to below 12 weeks of age.
II/0017	II - Other quality changes	18/06/2008	13/08/2008	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to remove the warnings "do not mix with butorphanol" and "do not mix with other medicinal products" from the SPC.
II/0016	II - Other quality changes	18/06/2008	13/08/2008	SPC	The European Commission amended the decision granting the marketing authorisation on the other quality changes

					related to rubber stopper.
IA/0015	1A-06-B Change in ATC code-vet product	08/02/2008	13/08/2008	SPC	The Agency accepted the variation on changing the ATCvet code.
IB/0014	1B-41-a-2 Change in pack size of finished product-change in number of units in pack	29/02/2008	13/08/2008	SPC, Labelling and PL	The Agency accepted the variation on changing the pack size of the finished product.
IB/0013	1B-14-a Change in manufacturer of active substance or starting material-change in site of manuf (replacement or addition)	08/02/2008	08/02/2008		The Agency accepted the variation on changing the manufacturer of the active substance.
IA/0012	1A-13-a Change in test procedure for active substance or starting material-minor changes test procedure	16/01/2008	16/01/2008		The Agency accepted the variation on changing the test procedure for the active substance.
IA/0011	1A-11-a Change in batch size of active substance or intermediate	16/01/2008	16/01/2008		The Agency accepted the variation on changing the batch size of the active substance and the intermediate.
IB/0010	1b-31-b Change to in-process tests or limits applied during the manufacture of the product	26/11/2007	26/11/2007		The Agency accepted the variation on changing an in-process control of the finished manufacturing process.
R/0009	Renewal of the marketing authorisation.	13/06/2007	02/08/2007	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Dexdomitor.
T/0008	Transfer of Marketing Authorisation	02/06/2006	11/07/2006		The European Commission accepted the transfer of the marketing authorisation.
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/10/2005	11/07/2006	PL	The EMEA notified the European Commission about changes in the list of local representatives. Amendments have been incorporated in the product literature and in the EPAR.
IA/0007	1A-28 Change in any part of the (primary) packaging material not in contact with finished product	06/12/2005	06/12/2005		The Agency accepted the variation on a change in the flip off lid of the aluminium cap.
II/0005	II - New Indication (same therapeutic area)	13/04/2005	24/06/2005	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on the additional indication for premedication in dogs before induction and maintenance of general anaesthesia.
IB/0004	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	28/07/2004	21/06/2005	SPC, Annex II, Labelling and PL	The Agency accepted the variation on the extension of the shelf-life to 3 years.
IA/0003	1A-04 Change in name and/or address of a manufacturer of the active substance	16/06/2004	16/06/2004		The Agency accepted the variation on a change in the name of the manufacturer of the active substance.
II/0002	II - New Indication (same therapeutic area)	14/01/2004	02/03/2004	SPC, Labelling and PL	The European Commission amended the decision granting marketing authorisation on the additional indication for deep sedation and analgesia in dogs in concomitant use with butorphanol for medical and minor surgical procedures, as well as a change of address of the distributor in Belgium and Luxembourg.

II/0001	II - New Indication (same therapeutic area)	09/04/2003	26/06/2003	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on the additional indication for cats (for premedication before induction and maintenance of general anaesthesia with the injectable dissociative agent ketamine) and also on the change the name, only, of the distributor in Iceland.