EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Novem

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]
WS/1813	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	20/05/2020		SPC and PL	The Agency accepted the variation to update section 4.5 of the SPC and section 12 of the package leaflet following assessment of a PSUR.
IG/1128/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.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	17/07/2019	n/a		n/a
IG/1031/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance	14/12/2018	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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	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				
IG/0831	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	01/09/2017	03/08/2018	PL	The Agency accepted the variation to delete the list of local representatives from the package leaflet.
IG/0813/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	13/07/2017	n/a		The Agency accepted the group of variations to register two additional testing sites for the finished product for the conducting of physical/chemical tests and the conducting of sterility tests.
X/0018	Annex I_2.(c) Change or addition of a new strength/potency	16/03/2017	15/05/2017	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add an extension to the authorisation for Novem 40 mg/ml for cattle.
IG/0722	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	27/09/2016	15/05/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
WS/0667	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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	12/02/2015	n/a		The Agency accepted the variation on the introduction of some minor changes of the manufacturing process at the new manufacturer.
WS/0661/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the	15/01/2015	18/12/2015	Annex II and PL	The Agency accepted the variation to register new manufacturing sites for bulk manufacturing, primary packaging, labelling and secondary packaging, final batch release and additional secondary packaging site. The company would also like to delete final batch release site. At the new manufacturing site, some minor changes related to in process controls, have been implemented compared to the specification of the current site.

	FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products 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.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing A.7 - Administrative change - Deletion of manufacturing sites B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
WS/0473/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	12/12/2013	n/a		The Agency accepted the variation to introduce a new specification parameter, to replace the current registered analytical method with a new method and to remove an obsolete test parameter in the 5 mg/ml presentations.
WS/0447/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	12/12/2013	n/a		The Agency accepted the variation to introduce a new specification parameter and to replace the current registered analytical method for the identity and assay test for ethanol with a new method for the 20 mg/ml presentations.
IG/0380	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	05/12/2013	n/a		The Agency accepted the variation to harmonise the Detailed Description of the Pharmacovigilance System (DDPS).

WS/0264	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	08/11/2012	10/12/2012	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on the addition of a new therapeutic indication ("dehorning claim") to the product information due to new clinical data.
IB/0010	C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH	16/12/2011	12/07/2012	SPC and PL	The Agency accepted the variation to implement a change following the assessment of a PSUR - additional information to be included in section 4.6 of the SPC 'Adverse Reactions'
IB/0009/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.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) 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	16/12/2011	12/07/2012	SPC, Labelling and PL	The Agency accepted the group of variations to change the shelf life of the finished product packed into 250 ml vials from 24 months to 36 months and to add four new pack sizes - multipack presentations of 12x20 ml, 12x50 ml, 12x100 ml and 6x250 ml.
II/0008/G	This was an application for a group of variations. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one 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	15/09/2010	14/10/2010	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on the addition of a new therapeutical claim for piglets and the addition of four new presentations for Novem 5 mg/ml. This decision was based on a positive opinion as adopted by CVMP on 15 September 2010.

	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				
II/0007	II - New presentation	11/02/2009	12/03/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on the addition of two new presentations (20 ml vial and 250 ml vial) and an update of testing specification for finished product and manufacturing specification.
R/0005	Renewal of the marketing authorisation.	12/11/2008	13/01/2009	SPC, Annex II, Labelling and PL	The European Commission has granted a renewal to the marketing authorisation.
IB/0006	1B-25-a-1 Change to comply with Eu. Ph. or with the national pharmacopoeia of a Member State	10/02/2008	10/12/2008		The Agency accepted the variation on the compliance of the active substance with the Ph. Eur.
II/0004	II - Other quality changes	19/07/2006	27/07/2006		The European Commission amended the decision granting the marketing authorisation on the use of an alternative rubber stopper.
X/0003	X-4-I Addition or change of target species	15/06/2005	25/08/2005	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add an extension to the authorisation for Novem 5 mg/ml to pigs.
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/02/2005	25/08/2005	PL	The EMEA accepted a notification of changes to the package leaflet.
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/06/2004	23/06/2004	PL	The EMEA accepted a notification of changes to the package leaflet.