Clomicalm

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]
IAIN/0039	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	21/10/2021		Annex II and PL	The Agency accepted the variation to change the manufacturer responsible for batch release of the finished product.
T/0037	Transfer of Marketing Authorisation	16/06/2021	13/07/2021	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Elanco GmbH', Germany to 'Virbac', France.
IB/0036/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	18/10/2020	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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IA/0035/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	26/06/2020	n/a		n/a
IB/0034/G	This was an application for a group of variations. B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.a.1.b - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in scoring/break lines intended to divide into equal doses	13/12/2019	09/03/2020	SPC and PL	The Agency accepted the group of variations to delete the imprints and a change to the score line intended to divide the tablets into equal doses
IA/0033/G	This was an application for a group of variations. 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) B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	31/10/2019	n/a		n/a
IA/0032	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	23/05/2019	n/a		The Agency accepted the variation to add a specification parameter for the potential residual solvent benzene.

II/0027	B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF	22/05/2019	n/a		The Agency accepted the variation to add a site responsible for the manufacturing of the active substance supported by an ASMF.
IB/0029/G	This was an application for a group of variations. B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.a.1.b - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in scoring/break lines intended to divide into equal doses B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	08/03/2019	09/03/2020	SPC and PL	The Agency accepted the group of variations to include minor changes to the manufacturing process and associated changes to the in-process tests; as well as changes to the imprints and score line intended to divide the 80 mg tablet.
T/0030	Transfer of Marketing Authorisation	18/12/2018	24/01/2019	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Elanco Europe Ltd' to 'Elanco GmbH'.

IG/1041/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	18/12/2018	n/a		n/a
IB/0028	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/10/2018	24/01/2019	SPC, Annex II, Labelling and PL	The Agency accepted the variation to update the product information in line with the latest QRD template (v.8.1) and to implement a number of administrative/formatting changes within the labelling.
IB/0026/G	This was an application for a group of variations. B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product B.II.d.1.i - Change in the specification parameters and/or limits of the finished product - Ph. Eur. 2.9.40 uniformity of dosage units is introduced to replace the currently registered method, either Ph. Eur. 2.9.5 or Ph. Eur. 2.9.6 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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 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.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number	17/04/2018	n/a		The Agency accepted the variation to register changes to the specifications and methods used for the quality control of the finished product.

IAIN/0025/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	24/07/2017	n/a		The Agency accepted the group of variations to add a site for primary and secondary packaging for all strengths of Clomicalm tablets
IA/0024/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	27/03/2017	n/a		The Agency accepted the group of variations to delete manufacturing sites in relation to the active substance.
WS/1074	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	19/01/2017	n/a		The Agency accepted the variation to update the pharmacovigilance system.

IB/0022/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 B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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.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.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	02/09/2016	n/a		The Agency accepted the group of variations relating to changes in the active substance section.
IG/0681	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	07/06/2016	13/06/2017	Annex II and PL	The Agency accepted the variation to change the name of the site responsible for manufacturing and batch release of the finished product
T/0020	Transfer of Marketing Authorisation	23/03/2016	18/04/2016	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Novartis Tiergesundheit GmbH' to 'Elanco Europe Ltd'.
IAIN/0019/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	26/02/2014	n/a		The Agency accepted variation to update DDPS to the latest version (ref version 2.3) including the change in the QPPV and QPPV contact details and/or back-up procedure.

IB/0018	C.I.8.b - Introduction of a new Pharmacovigilance system - which has been assessed by the relevant NCA/EMA for another product of the same MAH	30/08/2013	n/a		The Agency accepted a variation to introduce a new Detailed Description of the Pharmacovigilance System (DDPS) for Clomicalm.
R/0017	Renewal of the marketing authorisation.	13/02/2008	10/04/2008	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Clomicalm. In view of some reports on hepatic disorders, an additional warning was added to the SPC and product literature.
IA/0015	1A-01 Change in name and/or address of MAH	29/09/2005	25/01/2006	SPC, Labelling and PL	The EMEA approved a type IA variation (change of address of the marketing authorisation holder from Industriestrasse 30-34, 65760 Eschborn, Germany to Zielstattstrasse 40, 81379 München, Germany). Amendments have been incorporated in the relevant sections of the EPAR.
II/0014	II - Other quality changes	07/12/2005	25/01/2006	SPC, Labelling and PL	The European Commission approved a type II variation concerning the extension of the shelf life from 2 to 4 years. As a consequence, some other quality changes were made.
IA/0016	1A-05 Change in name and/or address of a manufacturer of the finished product	29/09/2005	29/09/2005		The EMEA approved a type IA variation (change of name of manufacturer of finished product from Novartis Santé Animal S.A. to Novartis Santé Animal S.A.S.). Amendments have been incorporated in the relevant sections of the EPAR.
II/0013	II - Other quality changes	17/03/2004	19/03/2004		The European Commission approved a type II variation concerning changes to several aspects of the quality of the product, such as update of a testing monograph in accordance with the revised European Pharmacopoeia, additional testing in accordance with the Japanese Pharmacopoeia, tightening of the specifications of the residual solvents and modification of the microbial limit tests. The variation did not require changes to the product literature.
R/0012	Renewal of the marketing authorisation.	12/02/2003	19/05/2003	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Clomicalm.
II/0011	II - Other quality changes	12/02/2003	27/02/2003		The European Commission approved a type II variation concerning changes to several aspects of the quality of the product, such as changes in raw material specifications, a change in description of the active substance manufacturing process, changes in the test methods and specification for the active substance, and changes in the test methods for the finished product. Amendments have been incorporated in the relevant sections of the EPAR.
I/0010	01_Change following modification(s) of the manufacturing authorisation(s)	26/06/2002	15/07/2002	Annex II, Labelling and PL	The EMEA approved a type I variation (deletion of 11 out of 12 batch release sites). Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.

II/0009	II - Other quality changes	09/01/2002	21/01/2002		The European Commission approved a type II variation increasing the specification of "further related substances" and "total further related substances" in relation to degradation products. This variation was a result of the evaluation of the Committee on the follow-up measures.
I/0007	08_Change in the qualitative composition of immediate packaging material	13/09/2000	08/12/2000	SPC	The EMEA approved a type I variation changing the qualitative composition of the immediate packaging material by removing a cotton plug. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/11/2000	15/11/2000	PL	The EMEA notified the European Commission of changes made to the package insert only. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
I/0006	17_Change in specification of the medicinal product	16/03/2000	27/03/2000		The EMEA approved a type I variation the specification of the medicinal product. Amendments have been incorporated in the relevant sections of the EPAR.
I/0005	25_Change in test procedures of the medicinal product	16/03/2000	27/03/2000		The EMEA approved a type I variation changing the test procedures of the finished product from using TLC to HPLC. Amendments have been incorporated in the relevant sections of the EPAR.
I/0003	31_Change in container shape	08/09/1998	21/02/2000		The EMEA approved a type I variation changing the container shape. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
I/0002	16_Change in the batch size of finished product	08/09/1998	21/02/2000		The EMEA approved a type I variation changing the batch size of the finished product. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
I/0001	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	08/09/1998	21/02/2000	Annex II	The EMEA approved a type I variation changing the content of the manufacturing authorisation. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/12/1999	03/02/2000	Labelling	Following a request by CVMP, the Commission adopted a decision to replace the wording of a warning on the carton box and the label with the text of the SPC: "Keep out of reach of children as accidental ingestion could be regarded as serious". Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.

I/0004	08_Change in the qualitative composition of immediate packaging material	28/09/1999	09/11/1999		The EMEA approved a type I variation changing the qualitative composition of the immediate packaging material by introducing a new seal. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.