EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Comfortis

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/0025/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol C.I.7.b - Deletion of - a strength B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation 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.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary	10/09/2021		SPC, Labelling and PL	The Agency accepted the group of variations to add a finished product (FP) manufacturer; to change the batch size (including batch size ranges) of the finished product - downscaling down to 10-fold; to change in-process tests or limits applied during the manufacture of the finished product - tightening of in-process limits; to change in-process tests or limits applied during the manufacture of the finished product; to change in test procedure for the finished product and to apply changes in imprints, bossing or other markings. In addition, the 90 mg strength was also removed.

[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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	packaging, for non-sterile medicinal products 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.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation				
IB/0027	C.I.3.z - Change(s) in the SPC, Labelling or PL of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR: implementation of wording agreed by the competent authority that does not require additional assessment	13/08/2021		SPC and PL	The Agency accepted the variation to implement the recommendation from CVMP based on the discussion outcome of the PSUR for the period 1 October 2019 - 30 September 2020. In addition, minor linguistic amendments and adjustment to latest QRD template have been introduced in different language versions of the PI.
IA/0026/G	This was an application for a group of variations. 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 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.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 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	30/07/2021	n/a		n/a
II/0023/G	This was an application for a group of variations. B.II.b.1.d - Replacement or addition of a manufacturing site for the FP - Site which requires an	15/04/2021	04/06/2021	SPC and Labelling	The Agency accepted the group of variations to add a manufacturing site for the finished product, to add a manufacturing site responsible for the stability testing of the finished product and consequential changes.

	initial or product specific inspection 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.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.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
IA/0024	A.7 - Administrative change - Deletion of manufacturing sites	17/03/2021	04/06/2021	Annex II and PL	The Agency accepted the variation to delete a site responsible for importation, batch control and batch release.
IAIN/0022/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.7 - Administrative change - Deletion of manufacturing sites	19/06/2020	04/06/2021	Annex II and PL	The Agency accepted the group of variations to change the name of a manufacturing site responsible for batch release, and to delete a manufacturing site.
IB/0021/G	This was an application for a group of variations.	03/04/2020	n/a		n/a

	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient 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 B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF 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.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				
IAIN/0020/G	This was an application for a group of variations. B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing 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	04/04/2019	01/04/2020	Annex II and PL	The Agency accepted the group of variations including the addition of a batch release and importation site.
IG/1040/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	17/12/2018	n/a		n/a

	the PhV system				
T/0018	Transfer of Marketing Authorisation	07/09/2018	24/09/2018	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Eli Lilly and Company Limited' to 'Elanco GmbH'.
WS/0906/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.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.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	14/07/2016	n/a		The Agency accepted the group of variations to change a testing facility for spinosad, to change the apporved stability protocol and other minor changes to both open and closed parts of the ASMF.
R/0015	Renewal of the marketing authorisation.	06/11/2015	07/01/2016	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Comfortis.
IB/0014	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	05/12/2014	07/01/2016	SPC and PL	The Agency accepted the variation to amend section 4.6 of the SPC.
IA/0013	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	23/05/2014	n/a		The Agency accepted the variation to make minor changes to the dissolution test carried out on the finished product and to the naming of the methods.
IG/0386	A.1 - Administrative change - Change in the name and/or address of the MAH	20/12/2013	11/12/2014	SPC, Labelling and PL	The Agency accepted the variation to align all products with MAH's full address.
X/0010	Annex I_2.(c) Change or addition of a new strength/potency	12/09/2013	13/11/2013	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for a line extension-addition of 180 mg tablets for dogs and cats.
IG/0364/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	31/10/2013	n/a		The Agency accepted the variation to change the QPPV and to update the DDPS.
IA/0009/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 of the finished	07/06/2013	n/a		The Agency accepted the group of variations to amend manufacturing site names.

	product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions				
X/0006/G	This was an application for a group of variations. X-3-III Extension to a new strength C.II.1 - Variations concerning a change to or addition of a non-food producing target species	08/11/2012	14/01/2013	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for a grouped variation - extension: addition of 90mg and 140mg tablets for dogs and cats and a type II variation to add cats as new target species for 270 and 425mg tablets.
IB/0008/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 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 C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)	07/11/2012	14/01/2013	SPC, Labelling and PL	The Agency accepted the group of variations to add a new pack size of 3 tablets for each strength, delete the 36 tablets pack size for each strength and to change the qualified person for pharmacovigilance.

IB/0007	B.II.b.5.f - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue	03/02/2012	n/a		The Agency accepted the variation to amend an in-process test limit.
IA/0005	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	28/10/2011	28/10/2011		The Agency accepted the variation to tighten the specification limits of the active substance.
IA/0004	B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions	30/09/2011	30/09/2011		The Agency accepted the variation on a minor change in the manufacturing process.
IAIN/0003	C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD	18/08/2011	18/08/2011		The Agency accepted the variation to add a contracting company to carry out pharmacovigilance database case entry and management.
IB/0002	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	30/06/2011	30/06/2011		The Agency accepted the variation on alternate strain in the manufacturing process of the active substance.
IAIN/0001/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.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	28/04/2011	28/04/2011		The Agency accepted the group of variations to add secondary manufacturing sites.