EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Convenia

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/0036	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	04/12/2020		SPC and PL	The Agency accepted the variation to implement changes to sections 4.5 and 4.6 of the SPC, and sections 6 and 12 of the package leaflet following assessment of a PSUR. The MAH took the opportunity to align the wording of section 13 of the package leaflet with the current QRD template.
IB/0035	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	30/04/2020		SPC, Labelling and PL	The Agency accepted the variation to correct translations and implement some minor QRD updates in EN PI. Additionally, the MAH is adding pictograms in the package leaflet.
IB/0034/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation 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	08/08/2018	n/a		The Agency accepted the group of variations relating to the addition of an alternate supplier of a starting material.

[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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IG/0951	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	05/07/2018	n/a		The Agency accepted the variation to update the current detailed description of the pharmacovigilance system (DDPS).
IB/0032/G	This was an application for a group of variations. 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.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	12/04/2018	11/04/2019	SPC, Labelling and PL	The Agency accepted the group of variations to make changes to the manufacturing process and to the immediate packaging of the finished product. Additionally, target species pictograms were included on the immediate label and the local representatives were deleted from the package leaflet. The product information was aligned with QRD template v8.1.
IG/0851	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)	15/11/2017	n/a		The Agency accepted the variation to change the name of the secondary packaging site.
IB/0029/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold	02/05/2017	n/a		The Agency accepted the grouped variation to add an additional supplier and to change the batch size of the active substance.
IG/0747	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	23/03/2017	04/04/2018	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
IA/0028	A.7 - Administrative change - Deletion of manufacturing sites	12/12/2016	n/a		The Agency accepted the variation to delete a supplier of starting material.
IB/0026	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	04/03/2016	n/a		The Agency accepted the variation to add an alternate test method.
IG/0542	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)	03/07/2015	n/a		The Agency accepted the variation to change the name of the site for the manufacturing of the finished product.
IB/0024	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	13/05/2015	n/a		The Agency accepted the variation to add a smaller batch size of 77.5 L for the registered 5 ml vials of Convenia 80 mg/ml powder and solvent for solution for injection for dogs and cats.
IG/0538	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	01/04/2015	n/a		The Agency accepted the variation to change the QPPV.
IG/0357/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a	31/10/2013	n/a		The Agency accepted the variation to add two manufacturing sites for secondary packaging.

	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				
II/0018	B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes	12/09/2013	n/a		The Agency accepted the variation to add a larger batch size of 179 litres (41,943 vials) to the existing batch size of 160 litres (36,810 vials).
IA/0020	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)	05/09/2013	27/08/2014	SPC, Annex II, Labelling and PL	The Agency accepted the variation to change the name and address of the finished product manufacturer.
IG/0328	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	05/09/2013	n/a		The Agency accepted the variation to update the contact details of the QPPV.
T/0019	Transfer of Marketing Authorisation	30/04/2013	16/05/2013	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Pfizer Ltd' to 'Zoetis Belgium SA'.
IA/0017	A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS	27/03/2013	n/a		The Agency accepted the variation to change the name of a site responsible for the manufacture of the active substance. The address remains the same.
II/0016	B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, and biological/immunological multidose parenteral medicinal products	13/04/2012	22/05/2012	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new presentation consisting of a 5 ml vial of lyophilised powder with a 10 ml vial of diluent.
IG/0005/G	This was an application for a group of variations. C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities	05/08/2011	05/08/2011		The Agency accepted the group of variations to change the location of the Qualified Person for Pharmacovigilance.
IA/0014	A.7 - Administrative change - Deletion of manufacturing sites	27/06/2011	27/06/2011		The European Medicines Agency accepted the variation to delete a manufacturing site of a diluent
IA/0013	A.7 - Administrative change - Deletion of manufacturing sites	16/06/2011	16/06/2011		The European Medicines Agency accepted the variation to delete a manufacturing site
R/0012	Renewal of the marketing authorisation.	07/04/2011	15/06/2011	SPC, Annex II, Labelling and PL	The European Commission approved an indefinite renewal for the product.
IB/0011	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	21/09/2010	14/04/2011	SPC and PL	The European Medicines Agency accepted the variation regarding changes to the terminology used in the indications section of the SPC and package leaflet.

II/0010	B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	14/07/2010	23/07/2010		The European Commission approved a type II variation for the use of an alternate stopper for use in the Convenia diluent vial. This alternate stopper is identical to that presently used by the manufacturer for other products supplied in the EU.
IA/0008	1A-05 Change in name and/or address of a manufacturer of the finished product	24/06/2009	15/01/2010	Annex II and PL	The EMEA approved a type IA variation (No. 5) to change the name of a manufacturer of the finished product.
IB/0007	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	07/07/2009	15/01/2010	SPC	The EMEA approved a type IB variation (No. 42.a.1) to increase the shelf life of finished product to 36 months.
II/0006	II - New Indication (same therapeutic area)	09/12/2009	15/01/2010	SPC, Labelling and PL	The European Commission approved a type II variation for an additional indication in dogs 'As adjunctive treatment to mechanical or surgical periodontal therapy in the treatment of severe infections of the gingiva and periodontal tissues associated with Porphyromonas spp. and Prevotella spp.'. The dose is a single subcutaneous injection of 8 mg/kg bodyweight (1 ml per 10 kg bodyweight). The product literature emphasises that the product should be used only for infections which require prolonged treatment (as the antimicrobial activity of Convenia following a single injection lasts for up to 14 days) and that 'The fundamental requirement of the treatment of periodontal disease is mechanical and/or surgical intervention by the veterinarian.'
II/0009	II - Other quality changes	14/10/2009	30/10/2009		The European Commission approved a type II variation for the addition of a new manufacturing site for the Convenia diluent and some associated manufacturing changes.
II/0003	II - Other quality changes	17/09/2008	22/10/2008	SPC	The European Commission approved a type II variation for an extension of the shelf-life of the product (to 30 months). Amendments have been included in the relevant sections of the Commission Decision and the EPAR.
II/0005	II - Other quality changes	15/10/2008	20/10/2008		The European Commission approved a type II variation for quality changes due to the addition of an alternative finished product manufacturing site.
IB/0004	1B-07-c Replacement or addition of a manufacturing site for part or all of manufacturing process	16/09/2008	16/09/2008		The EMEA approved a type IB variation (No. 7.c) for an additional manufacturing site for several stages of the manufacture of the finished product.
II/0001	II - Other quality changes	18/06/2008	25/06/2008		The European Commission approved a type II variation for an additional supplier of the starting material.
II/0002	II - New safety warning	16/04/2008	03/06/2008	SPC and PL	The European Commission approved a type II variation for the inclusion of an additional statement in the SPC and package leaflet regarding possible very rare gastrointestinal reactions. Amendments have been incorporated into the relevant sections of the Commission Decision and of the

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