Equilis Prequenza

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/1836	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	05/11/2020		SPC, Annex II, Labelling and PL	The Agency accepted a variation to add a manufacturing site for the two equine influenza virus strains. In addition, Annex II was updated and a QRD update and editorial changes were made to the product information.
IG/1104	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	20/05/2019	18/05/2020	SPC	The Agency accepted the variation to amend section 4.9 of the SPC to harmonise with the advice in section 9 of the package leaflet.
IG/0967/G	This was an application for a group of variations. 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	26/07/2018	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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	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/0718/G	This was an application for a group of variations. 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	22/09/2016	n/a		n/a
II/0010	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	11/09/2014	n/a		The Agency accepted the variation to lower the end-of-shelf-life limit of the adjuvant component saponin fraction C.
IG/0465	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	20/08/2014	n/a		The Agency accepted the variation to change the qualified person for pharmacovigilance (QPPV).
X/0007/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol B.II.a.3.b.3 - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Change (replacement) to a biological/immunological/ immunochemical test method or a method using a biological reagent for a biological AS 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.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological medicinal	07/02/2013	10/04/2013	SPC	The European Commission amended the decision granting the marketing authorisation to change the source material used to produce the antigens; to change the equine influenza strain of the vaccine; to replace the master seed of of the equine influenza strain; and to implement changes to the manufacturing process.

	product and is not related to a protocol C.II.5 - Variations concerning the replacement of a strain for a veterinary vaccine against equine influenza B.I.b.z - Change in control of the AS - Other variation B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological medicinal product and is not related to a protocol B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits Annex I_1.(c) Replacement of a biological AS with one of a slightly different molecular structure				
IG/0127	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	06/01/2012	n/a		The Agency accepted a varaition to change the name and address of a manufacturer of the active substance.
II/0006	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	09/06/2011	09/06/2011		The European Medicines Agency accepted a Type II variation to amend the potency test limits for the equine influenza components
R/0005	Renewal of the marketing authorisation.	19/05/2010	27/07/2010		The European Commission renewed the marketing authorisation for Equilis Prequenza.
II/0004	II - Other quality changes	11/02/2009	23/03/2009	SPC and PL	The European Commission issued a decision on a type II variation for amendment of adverse reactions section in SPC and package leaflet.
II/0003	II - New Quality Control Method	14/05/2008	21/05/2008		The European Commission issued a decision on a type II variation for a change to the finished product control test of the adjuvant by replacing the qualitative by quantitative determination.
II/0002	II - Other quality changes	14/03/2007	19/03/2007		The European Commission approved a type II variation, regarding an increase in the maximum limits for the live titre of Equine influenza viruses before inactivation and to increase the shelf life of the adjuvant before use in the final product.
IB/0001	1B-41-a-2 Change in pack size of finished product-change in number of units in pack	12/01/2006	12/01/2006	SPC, Labelling and PL	The EMEA accepted a type IB variation to add two new presentations: 1 or 5 pre-filled syringes with needles.