ProteqFlu-Te

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]
II/0030/G	This was an application for a group of variations. B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing including a biological/immunological/ immunochemical method takes place 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	17/02/2021		Annex II	The Agency accepted a group of variations to transfer a part of the manufacturing and quality control of the active ingredient *Clostridium tetani* to an external partner based in Spain.
IG/1337	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	10/02/2021	n/a		n/a
IG/1279	A.7 - Administrative change - Deletion of manufacturing sites	14/08/2020	n/a		n/a
IG/1264	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	29/07/2020		Annex II	The Agency accepted the variation to change the name of a site responsible for the manufacture of the active

[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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	or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				substance.
IG/1242	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	15/05/2020		Annex II	The Agency accepted the variation to change the name of a site responsible for the manufacture of the active substance.
IG/1230	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)	08/04/2020	n/a		n/a
IG/1204/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.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)	20/03/2020		Annex II and PL	The Agency accepted the group of variations to change the names of the site responsible for batch release of the finished product and the site responsible for packaging of the finished product.
T/0024	Transfer of Marketing Authorisation	06/12/2019	15/01/2020	SPC, Annex II, Labelling and PL	The European Commission transferred the marketing authorisation from 'Merial SAS' to 'Boehringer Ingelheim Vetmedica GmbH'.
IG/1127/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	10/07/2019	n/a		n/a
WS/1366	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.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	19/04/2018	n/a		n/a

WS/1195	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol	15/02/2018	n/a		n/a
WS/1095	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.2.z - Changes in the manufacturing process of the AS - Other variation	15/06/2017	n/a		n/a
IA/0019	B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	20/06/2016	n/a		n/a
IG/0592	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	04/09/2015	n/a		n/a
II/0017	C.II.5 - Variations concerning the replacement of a strain for a veterinary vaccine against equine influenza	05/06/2014	11/07/2014	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to substitute the strain vCP1533 by the strain vCP3011 in compliance with the OIE Expert Surveillance Panel on equine influenza vaccine composition.
R/0015	Renewal of the marketing authorisation.	10/01/2013	06/03/2013	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for ProteqFlu-Te.
IB/0016	B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place	07/12/2012	n/a		The European Medicines Agency accepted a variation to transfer the site of a safety test on horses.
IB/0014	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	17/08/2012	n/a		The Agency accepted a type IB variation to make a minor change in the manufacturing process of the active substance purified Clostridium tetani toxoid component.
IB/0012	B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer	06/10/2011	06/10/2011		The European Medicines Agency accepted a type IB variation to update a TSE/BSE European Pharmacopeia certificate of suitability.
II/0011	C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	07/04/2011	18/05/2011	SPC and Annex II	The European Commission approved a type II variation to extend the duration of immunity against tetanus of ProteqFlu-Te to 2 years. This change impacts on the vaccination scheme of ProteqFlu-Te as well as the

					vaccination scheme of ProteqFlu since an alternative vaccination with ProteqFlu and ProteqFlu-Te will be recommended.
II/0010	II - Other quality changes	10/02/2010	15/02/2010		The European Commission approved a type II variation for an alignment of the product's specifications with shelf-life (increase of minimum release titre) and a review of target formulation for flu components vCP1533 and vCP2242.
X/0007	X-1-III Quantitative change to the active substance(s)	12/03/2008	25/04/2008	SPC, Labelling and PL	The European Commission approved an extension of the Community marketing authorisation for ProteqFlu-Te to substitute the vCP1529 strain (Kentucky) with the vCP2242 strain (Ohio). Amendments have been incorporated to the relevant sections of the Commission Decision and the EPAR.
II/0008	II - Other quality changes	12/12/2007	22/01/2008	Annex II	The European Commission approved a type II variation for the relocation of the active substance production site.
R/0009	Renewal of the marketing authorisation.	07/11/2007	11/01/2008	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation of ProteqFlu-Te.
II/0006	II - Other quality changes	12/09/2007	29/10/2007	SPC, Labelling and PL	The European Commission approved a type II variation to decrease the target formulation titre for the two active ingredients vCP1529 and vCP1533, as well as to delete the freeze-dried presentations.
X/0005	X-3-IV Change or addition of a new pharmaceutical form	07/12/2005	13/02/2006	SPC, Labelling and PL	The European Commission approved an extension of the Community marketing authorisation for ProteqFlu-Te to a new pharmaceutical form (suspension for injection) and a decrease in the minimum protective dose. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.
II/0004	II - Other quality changes	10/11/2004	05/01/2005	SPC, Annex II, Labelling and PL	The European Commission approved a type II variation to change the manufacturing site for the tetanus active ingredient and delete the list of local representatives from the package insert. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.
I/0003	03_Change in the name and/or address of the marketing authorisation holder	12/09/2003	17/10/2003	SPC, Labelling and PL	The EMEA accepted a type I variation to change the address of the marketing authorisation holder whilst remaining the same legal entity.
I/0002	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	12/09/2003	17/10/2003	SPC, Labelling and PL	The EMEA accepted a type I variation to change the batch release site.
I/0001	11b_Change in supplier of an intermediate compound used in manufacture of the active substance	04/06/2003	04/06/2003		The EMEA approved a type I variation (No 11b) to add four TSE certified calf serum suppliers. Amendments have been incorporated into the relevant sections of the Commission

					Decision and of this EPAR.