Equip WNV

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
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		SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives.
IB/0023	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	12/02/2016	27/02/2017	SPC and PL	The Agency accepted a variation to extend the shelf life of the finished product from 18 months to 2 years.
IB/0022/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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) B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) B.II.f.1.b.5 - Stability of FP - Extension of the shelf	04/12/2015	18/12/2015	SPC, Annex II, Labelling and PL	The Agency accepted a group of variations which included extending the shelf life of the finished product, deletion of manufacturing sites and deletion of pack sizes.

[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] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material)				
IA/0021	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	26/06/2015	18/12/2015	Annex II and PL	The Agency accepted a variation to change the name of a manufacturing site.
WS/0649/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.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	10/04/2015	n/a		The Agency accepted the variation to change the site for testing of starting materials of biological origin and consequential change in test procedure.
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.
II/0018/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method B.II.b.3.c - Change in the manufacturing process of the finished or intermediate product - The product is a biological/immunological medicinal product and the	11/12/2014	18/12/2015	SPC, Annex II, Labelling and PL	The Agency approved a group of variations to add an additional manufacturer of the finished product and for batch release, testing and secondary packaging. Several consequential changes are also included.

	change requires an assessment of comparability 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.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.c.2.a - Change in test procedure for an excipient - 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.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products 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				
IG/0359	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	25/10/2013	n/a		The Agency accepted a variation to add a manufacturing site for secondary packaging of the finished product.
II/0012	C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	12/09/2013	11/10/2013	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new indication.
R/0014	Renewal of the marketing authorisation.	18/07/2013	12/09/2013	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Equip WNV.
IA/0015	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	05/09/2013	11/10/2013	SPC, Annex II, Labelling and PL	The European Medicines Agency accepted the type IA variation to change the name of the active substance 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 a variation to update the contact details of the QPPV.
T/0013	Transfer of Marketing Authorisation	30/04/2013	27/05/2013	SPC, Labelling and PL	The European Commission aproved a transfer of the marketing authorisation from 'Pfizer Ltd' to 'Zoetis Belgium SA'.
IA/0011	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)	03/01/2013	n/a		The European Medicines Agency accepted a variation to remove the Rinderpest testing from the bovine raw material testing specifications.
II/0010	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	08/11/2012	27/05/2013	Annex II	The Agency accepted the variation to add a manufacturing site for preparation of the active substance.

	[-] used in the manufacture of a biological/immunological product				
IAIN/0009	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	17/02/2012	22/05/2012	SPC, Annex II, Labelling and PL	The European Medicines Agency accepted a type IA(IN) variation to change the name of the product from "Duvaxyn WNV" to "Equip WNV."
II/0006	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	13/04/2012	22/05/2012	Annex II	The Agency accepted the variation to change the manufacturer of the active substance.
IA/0008	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	15/12/2011	n/a		The European Medicines Agency accepted a type IA variation to tighten the specification limits
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 a group of variations to change the location of the Qualified Person for Pharmacovigilance.
T/0004	Transfer of Marketing Authorisation	22/10/2010	13/01/2011	SPC, Annex II, Labelling and PL	The European Commission approved a transfer of the marketing authorisation from "Fort Dodge Animal Health Ltd" to "Pfizer Ltd".
IA/0003/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 product, including quality control sites (excluding manufacturer for batch release) A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	17/09/2010	13/01/2011	Annex II and PL	The European Medicines Agency accepted a group of type IAIN and type IA variations to update the name of the manufacturer responsible for batch release; and to update the name of the manufacturer responsible for the active substance.
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/09/2009	13/01/2011	PL	The European Medicines Agency notified the European Commission about the addition of the list of local representatives. Amendments have been incorporated in the product literature and in the EPAR.
IB/0005	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	19/11/2010	19/11/2010		The European Medicines Agency accepted a type IB variation for the provision of a new pharmacovigilance system associated with the transfer of the marketing authorisation from "Fort Dodge Animal Health Ltd" to "Pfizer Limited".
IB/0002	B.I.a.z - Change in manufacture of the AS - Other variation	15/09/2010	15/09/2010		The Agency accepted a type IB variation to provide clarifications on the materials listed under sections C1 and C2 of the Part II dossier.