

Equip WNV

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
IAIN/0009	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	17/02/2012	n/a	SPC, Annex II, Labelling, PL	The European Medicines Agency accepted a Type IA(IN) variation to change the name of the product from Duvaxyn WNV to Equip WNV.
IA/0008	B.1.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		
IG/0005/G	This was an application for a group of variations. C.1.9.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 European Medicines Agency accepted a type IA variation to change the location of the Qualified Person for Pharmacovigilance.
IA/0003/G	This was an application for a group of variations.	17/09/2010	13/01/2011	Annex II, PL	The European Medicines Agency accepted a group of a type IAIN variation to update the name of the

¹ Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.

² No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.

³ SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



No	Scope	Opinion/ Notification ¹ issued on	Commission Decision Issued ² / amended on	Product Information affected ³	Summary
	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible 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)				manufacturer responsible for batch release from "Fort Dodge Laboratories (Ireland)" to "Elanco Animal Health Ireland Limited"; and a type IA variation to update the name of the manufacturer responsible for the active substance from "Fort Dodge Animal Health" to "Boehringer Ingelheim Vetmedica Inc".
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.
T/0004	Transfer of Marketing Authorisation	22/10/2010	13/01/2011	SPC, Annex II, Labelling, PL	The European Commission approved a transfer of the marketing authorisation from "Fort Dodge Animal Health Ltd" to "Pfizer Ltd".
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 European Medicines Agency accepted a type IB variation clarifying that the materials listed under sections C1 and C2 of the Part II dossier (utilised in the production of the antigen either directly or within the formulation of the medias and solutions) are prepared and supplied by the Charles City site for the Fort Dodge site. This update has no effect on the SPC or Annex II/III of the QRD.