EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Netvax

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
IB/0006	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	14/10/2011	14/10/2011	SPC, Labelling, PL	The European Medicines Agency accepted a type IB variation for a change to in-use shelf life of finished product from "use immediately" to "use within 8 hours".
IA/0005/G	This was an application for a group of variations. B.III.1.b.2 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer, B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer	04/04/2011	04/04/2011		The European Medicines Agency accepted a group of type IA variations to provide new and updated certificates of suitability.

[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).

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II/0003	B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS	10/11/2010	17/11/2010		The European Commission approved a type II variation regarding a change to in-process tests applied during the manufacture of the active substance.
II/0002/G	This was an application for a group of variations. B.II.b.3.c - Change in the manufacturing process of the finished product - The product is a biological/immunological medicinal product and the change requires an assessment of comparability, 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	11/11/2010	17/11/2010		The European Commission approved a grouping of a type II for a change in the manufacturing process of the finished product and a type IA variation for a change to in-process tests or limits applied during the manufacture of the finished product.
IA/0004	B.III.1.b.2 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	31/05/2010	31/05/2010		The European Medicines Agency accepted a type IA variation for the submission of a new or updated Ph.Eur certificate of suitability to add additional suppliers of materials of animal origin.

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IG/0001/G	This was an application for a group of variations. C.I.9.i - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	07/05/2010	07/05/2010		The European Medicines Agency accepted a group of type IA variations to update the QPPV.