Nobilis IB 4-91

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
IAIN/0025	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	21/01/2019		SPC, Labelling and PL	The Agency accepted the variation to update the product information with a user safety precaution following the latest PSUR assessment.
IAIN/0024	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	29/11/2017	17/12/2018		The Agency accepted the variation to add a new pack-size of 10 cups of 2,500 doses for Nobilis IB 4-91.
IG/0802	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	16/05/2017	n/a		The Agency accepted a variation to add a supplier of packaging components of the cup/lid which are used for storage of the finished product.
IB/0022/G	This was an application for a group of variations. B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the	15/07/2016	18/01/2017	SPC	The Agency accepted the group of variations to provide supplementary information for the lid of the foil cup (immediate packaging), to amend the specification for the type of glass of the glass vials of the immediate packaging; and to extend the shelf life of the finish product presented in cups to 24 months when stored at 2 - 8 °C.

[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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

	finished product - Other variation 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				
II/0021/G	This was an application for a group of variations. 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 change requires an assessment of comparability B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits 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.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	21/01/2016	18/01/2017	SPC, Labelling and PL	The Agency accepted the variation to introduce a lyophilisate with a new appearance presented in a new container (sphereons).
IB/0020	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	07/07/2015	n/a		The Agency accepted the variation to introduce a PCR test as an alternative to the conventional mycoplasma FPC test (culture method).
WS/0607	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	12/03/2015	13/05/2015	SPC and PL	The Agency accepted the variation to add a claim for the mixed-use of Nobilis IB 4-91 and Nobilis IB Ma5.
IG/0420	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	04/04/2014	13/05/2015	SPC, Annex II, Labelling and PL	The Agency accepted the variation to add the product information in the Croatian language as approved during PALCIII to the Annexes to the Commission Decision.
II/0015/G	This was an application for a group of variations. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	16/05/2012	28/06/2012	SPC and PL	The European Commission amended the decision granting the marketing authorisation to include vaccination at day old for layers and breeders.
IG/0128	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)	06/01/2012	n/a		The Agency accepted a group of type IA variations to change the name and address of a manufacturer of the finished product.

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 variation to change the name and address of a manufacturer of the active substance.
R/0014	Renewal of the marketing authorisation.	12/03/2008	21/05/2008	SPC, Annex II, Labelling and PL	The European Commission approved the renewal of the marketing authorisation.
II/0012	II - Other quality changes	11/07/2007	19/07/2007		The European Commission amended the decision granting the marketing authorisation to add an alternative site for final product quality control testing and to implement the Ph. Eur 2.6.25 for extraneous agents testing.
IA/0013	1A-22-a Submission of a new or updated TSE Eu. Ph. certificate of suitability for an excipient	25/05/2007	25/05/2007		The Agency accepted the variation to add a new TSE European Pharmacopoeia certificate of suitability for hydrolysed gelatine.
II/0010	II - Other quality changes	13/07/2005	18/07/2005		The European Commission amended the decision granting the marketing authorisation to change a stabilizer for freeze-drying.
II/0009	II - Other quality changes	09/03/2005	18/03/2005		The European Commission amended the decision granting the marketing authorisation to include an additional antigen manufacturing site.
II/0008	II - Other quality changes	07/09/2004	20/10/2004		The European Commission amended the decision granting the marketing authorisation to waive the routine application of the batch safety test.
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/03/2004	14/04/2004	PL	The Agency accepted a change in the package insert (deletion of the list of local representatives). Amendments have been made to the relevant sections of the EPAR.
II/0006	II - New Indication (same therapeutic area)	12/11/2003	29/01/2004	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to remove a contra-indication related to layer and breeder birds.
R/0005	Renewal of the marketing authorisation.	14/05/2003	10/07/2003	SPC, Labelling and PL	The European Commission approved the renewal of the marketing authorisation.
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/07/2000	09/10/2000	PL	The Agency notified the European Commission of a change to the package insert relating to local representatives.
I/0002	30_Change in pack size for a medicinal product	08/03/1999	11/05/1999	SPC, Labelling and PL	The Agency accepted a type I variation to add a further pack size (multi-pack of 10 vials of 500 doses).
I/0001	30_Change in pack size for a medicinal product	08/03/1999	11/05/1999	SPC, Labelling and PL	The Agency accepted a type I variation to add a further pack size (vial of 500 doses).