Nobilis IB Primo QX

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/0009/G	This was an application for a group of variations. 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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.e.6.z - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Other variation 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	20/01/2021		SPC, Labelling and PL	The group of variations is to add Merck Sharp & Dohme Animal Health, S.L., Salamanca, Spain (SAL) as manufacturing site of the sphereons in cups and as secondary packaging site for Nobilis IB Primo QX, to introduce polyethylene terephthalate (PET) plastic boxes as a secondary outer packaging: introduction of new EU numbers, pack size outside the range of the currently approved pack sizes and introduction of pack size within the range of currently approved pack sizes; to add identity test by PCR; to optimise the test method of PCR mycoplasma test; to change the range of residual moisture limit; to add in process control (IPC) test ; to change the release requirement of the virus titration test (on spheres, IPC test), the batch size of the vaccine suspension for the SAL site, the hold time of harvested allantoic fluid containing the active substance and the sterilisation method: sterilisation of cup and lid by beta-irradiation. In addition, the applicant took the opportunity to introduce a few minor editorial changes in different dossier sections.

[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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	(including replacement or addition) B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range 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.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line) B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation 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 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 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				
II/0008	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/09/2020		SPC and PL	The Agency accepted the variation is to present new data on the safe use of Nobilis IB Primo QX during the laying period with the purpose to remove the warning in the relevant sections of the SPC and package leaflet.
IB/0007	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	30/07/2019	12/08/2020	SPC	The Agency accepted the variation to extend the shelf life of the finished product from 15 to 24 months.
R/0006	Renewal of the marketing authorisation.	21/03/2019	13/06/2019	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Nobilis IB Primo QX.
IG/0967/G	This was an application for a group of variations. 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	26/07/2018	n/a		n/a

	system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system				
IAIN/0004	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	04/12/2017	18/12/2018	SPC, Annex II, Labelling and PL	The Agency accepted the variation to add a new presentation of 2,500 doses.
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 the variation to add a supplier of packaging components of the cup/lid which are used for storage of the finished product.
IG/0718/G	This was an application for a group of variations. 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	22/09/2016	n/a		n/a
IB/0001	B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation	15/07/2016	14/07/2017	SPC	The Agency accepted the variation to provide supplementary information for the lid of the foil cup (immediate packaging).