Hiprabovis IBR Marker Live

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/0793	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	22/06/2017		Annex II	The Agency accepted a variation to change the address of the manufacturer of the biological active substance.
R/0007	Renewal of the marketing authorisation.	10/09/2015	06/11/2015	SPC, Annex II, Labelling and PL	The Commission adopted the renewal of the marketing authorisation for the product.
II/0005	B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	08/10/2015	n/a	SPC	The agency approved a variation to include all presentations of the solvent (10 ml, 50 ml and 100 ml container containing 60 ml of solvent) in polyethylene terephthalate (PET) containers.
IG/0565	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	24/07/2015	06/11/2015	PL	The Agency accepted a variation for a change in the list of local representatives.
II/0006	B.I.a.1.e - Change in the manufacturer of AS or of a	09/07/2015	06/11/2015	Annex II	The Agency approved a variation to add the address of the

[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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	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				antigen production plant.

Application number	Scope	Opinion / Notification[4] issued on	Commission Decision Issued[5] / amended on	Product Information affected[6]	Summary
II/0003/G	This was an application for a group of variations. B.I.d.1.b.2 - Stability of AS - Change in the storage conditions - Change in storage conditions of biological/immunological ASs, when the stability studies have not been performed in accordance with a currently approved stability protocol B.I.d.1.b.2 - Stability of AS - Change in the storage conditions - Change in storage conditions of biological/immunological ASs, when the stability studies have not been performed in accordance with a currently approved stability protocol	11/09/2014	n/a		The Agency accepted the variation to change the storage conditions of the inoculum to -80°C and to extend the storage period of both the pre-inoculum and the inoculum up to 24 months.
IB/0002	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	19/07/2013		SPC	The Agency accepted a variation to extend the shelf life of the solvent from 2 years to 5 years.
II/0001	B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, and biological/immunological multidose parenteral medicinal products	10/11/2011	09/01/2012	SPC, Labelling and PL	The European Medicines Agency accepted a type II variation for the addition of a 30 dose presentation.

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[5] 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.
[6] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).