

## Virbagen Omega

### Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued / amended on	Product Information affected <sup>2</sup>	Summary <sup>3</sup>
IG/1409	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	07/10/2021		PL	The Agency accepted the variation to update the list of local representatives.
IB/0009	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	21/09/2018	04/10/2019	SPC, Labelling and PL	The Agency accepted the variation to update the storage temperature, to align the Product Information with the latest QRD template and to slightly update the local representatives.
IG/0724	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	21/12/2016	12/01/2018	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
WS/0929/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.  B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile	06/10/2016	n/a		The Agency accepted the group of variations to add new manufacturing sites.

<sup>1</sup> 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.

<sup>2</sup> SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

<sup>3</sup> Since October 2019 summary information is no longer published for variations that do not impact upon the product information

	medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation				
IA/0006	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	19/05/2011	05/08/2011	Annex II	The Agency accepted the variation to clarify the address of the active substance manufacturer.
II/0005	II - Other quality changes	12/03/2008	17/04/2008	SPC	The European Commission amended the decision granting the marketing authorisation to replace the stoppers used to close the freeze dried fraction, for the adjustment step during the bulk formulation and for an additional control to guarantee the absence of virus plant contamination in the active ingredient.
R/0004	Renewal of the marketing authorisation.	13/09/2006	20/11/2006	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation indefinitely for Virbagen Omega.
IA/0003	1A-41-a-1 Change in pack size of finished product-change in number of units in a pack	07/02/2005	26/08/2005	SPC, Labelling and PL	The Agency accepted the variation to add two presentations - a carton containing 1 vial of powder and solvent and a carton containing 2 vials of powder and solvent to the 10 MU product. Amendments have been made to the relevant sections of the EPAR.
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/12/2004	26/08/2005	Labelling and PL	The EMEA accepted a notification for the addition of the local representatives on the Package Insert. Amendments have been made to the relevant sections of the EPAR.
X/0001	X-4-I Addition or change of target species	14/04/2004	29/07/2004	SPC, Labelling and PL	The European Commission adopted a decision for the extension application to add cats as a new target species.