Abrysvo

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
IB/0003/G	This was an application for a group of variations. B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.7.a - Change in supplier of packaging	18/03/2024	n/a		

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	components or devices (when mentioned in the dossier) - Deletion of a supplier B.II.e.z - Change in container closure system of the Finished Product - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation				
IA/0004	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	07/03/2024	n/a		
II/0001	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 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	22/02/2024		SmPC, Labelling and PL	The SmPC sections 6.5, 6.6 and 8 have been updated as follows: Addition of a new presentation of Abrysvo powder and solvent for solution for injection (EU/1/23/1752/007) with the new container closure (glass vial) and the pack size of 5 diluent vials + 5 antigen vials. The Labelling and PL have been updated accordingly.