Fulphila

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Article 61(3) /	- Notification acc. Article 61(3) - Accepted	17/02/2026		PL	

[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).

EMA/N/0000326669	Update of the package leaflet with revised contact details of local representatives.				
Variation type IA / EMA/VR/0000323623	This was an application for a group of variations. B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.b Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.I.c.2 Change in the specification parameters and/or limits of the immediate packaging of the active substance - B.I.c.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active	28/01/2026			

	substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.2 Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.z To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and immediate packaging materials - Accepted B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.z To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and				

	immediate packaging materials - Accepted B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.z To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and immediate packaging materials - Accepted B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.z To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and immediate packaging materials - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.c Addition of a new specification parameter to the specification with its corresponding test method - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.b Tightening of specification limits - Accepted B.III.2 Change to comply with Ph. Eur. or				

	with a national pharmacopoeia of a Member State - B.III.2.z To reflect compliance with the Ph.Eur. and remove reference to the internal test method and test method number for active substances, excipients, active substance starting materials and immediate packaging materials - Accepted B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.z - To more accurately describe the appearance of active substance, starting material, intermediate or reagent - Accepted				
Variation type IB / EMA/VR/0000246580	This was an application for a group of variations. B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.e The scale for a biological/immunological active substance is increased / decreased without process change (e.g. duplication of line) - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.2 Changes in the manufacturing	03/03/2025			

	process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted				
Variation type IA / EMA/VR/0000244618	B.II.e.7 Change in supplier of packaging components or devices (when mentioned in the dossier) - B.II.e.7.b Replacement or addition of a supplier - Accepted	15/01/2025			
PSUR / EMA/PSUR/0000274399					