



Sondelbay

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 |
|--------------------|--|--|--|---|---------|
| N/0004 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 11/06/2024 | | PL | |
| IB/0005 | B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation | 22/05/2024 | 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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|-----------|---|------------|-----|--|--|
| IA/0003/G | <p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> | 26/04/2024 | n/a | | |
| IA/0002 | <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> | 02/08/2023 | n/a | | |
| IB/0001/G | <p>This was an application for a group of variations.</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> | 23/06/2023 | n/a | | |