# Enspryng

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/0014 | B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol | 27/09/2024 | | SmPC and Labelling | |
| PSUSA/10944 | Periodic Safety Update EU Single assessment - | 13/06/2024 | n/a | | PRAC Recommendation - maintenance |

[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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| /202311 | satralizumab (for centrally authorised products) | | | | |
| PSUSA/10944 /202305 | Periodic Safety Update EU Single assessment - satralizumab (for centrally authorised products) | 11/01/2024 | n/a | | PRAC Recommendation - maintenance |
| IB/0011/G | This was an application for a group of variations.<br><br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure<br>B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits<br>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate | 24/10/2023 | n/a | | |
| IB/0009 | B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data | 08/08/2023 | n/a | | |
| PSUSA/10944 /202211 | Periodic Safety Update EU Single assessment - satralizumab (for centrally authorised products) | 06/07/2023 | n/a | | PRAC Recommendation - maintenance |
| IB/0006 | B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS | 20/04/2023 | n/a | | |

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| N/0008 | Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification) | 17/03/2023 | | PL | |
| PSUSA/10944 /202205 | Periodic Safety Update EU Single assessment - satralizumab (for centrally authorised products) | 12/01/2023 | n/a | | PRAC Recommendation - maintenance |
| PSUSA/10944 /202111 | Periodic Safety Update EU Single assessment - satralizumab (for centrally authorised products) | 07/07/2022 | n/a | | PRAC Recommendation - maintenance |
| IB/0003/G | This was an application for a group of variations.<br><br>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process<br>B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test<br>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process | 24/02/2022 | n/a | | |
| IB/0002 | B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation | 11/08/2021 | n/a | | |
| IB/0001 | B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes | 26/07/2021 | 30/06/2022 | SmPC, Labelling and PL | |