# Cejemly

## 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, please 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) - | 03/04/2025 | | 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).

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| EMA/N/0000261048 | Update of the package leaflet to add a list of local representatives. Additionally, the MAH took the opportunity to align the revision date format of the package leaflet with the latest QRD template and to introduce minor editorial amendments to the Slovenian and Czech package leaflet. | | | | |
| Variation type IA / EMA/VR/0000263406 | B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.a Tightening of in-process limits - Accepted | 01/04/2025 | N/A | | |
| Marketing Authorisation Transfer - H / EMA/T/0000244822 | - Transfer of a marketing authorisation -<br><br>Transfer of marketing authorisation from SFL Pharmaceuticals Deutschland GmbH to CStone Pharmaceuticals Ireland Limited | 04/02/2025 | 10/03/2025 | SmPC, Labelling and PL | |