Silodosin Recordati

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
Article 61(3) / EMA/N/0000255260	- Notification acc. Article 61(3) - Update of the package leaflet to delete United Kingdom (Northern Ireland) from the list of local representatives to comply with the Windsor Framework for labelling and packaging of medicines (QRD template	10/03/2025		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).

	10.4). Additionally, the MAH took the opportunity to introduce minor editorial amendments to the English text of the package leaflet with consequential amendments to all other language versions.				