Vydura

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
Variation type IB /	This was an application for a group of	11/04/2025		SmPC, Annex	

[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/VR/0000254589	variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.a The activities for which the manufacturer/importer is responsible include batch release - Accepted Type IB (C.1.z): To update section 5.2 of the (PK properties) to align the SmPC with the company Core Data Sheet. In addition, the MAH updated the company name of the Pfizer Ireland local representative is section 6 of the Package Leaflet and aligned the PI to the latest QRD update (10.4).+ Type IAIN (A.5.a): To change the legal entity name of the currently registered drug product batch release and secondary packaging site from Pfizer Ireland Pharmaceuticals, Newbridge, Ireland to Pfizer Ireland Pharmaceuticals Unlimited Company, Newbridge, Ireland.			II and PL	