Taxotere

Procedural steps taken and scientific information after the authorisation*

*Due to Agency`s update of its procedure management systems, an additional document, capturing the historical lifecycle may be available in the 'Assessment history' section. For the complete 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 IA /	B.III.1.a European Pharmacopoeial	16/07/2024	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).

EMA/VR/0000221440	Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted				
Article 61(3) / EMA/N/0000220958	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representative	30/07/2024		PL	