EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Docefrez

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IB/0001	To add a new therapeutic indication for Docefrez 20 mg and 80 mg powder and solvent for concentrate for solution for infusion, following the same change for the reference product Taxotere. Minor linguistic amendments are included. In addition, the list of local representatives in the Package Leaflet as well as the EU numbers and date of the marketing auhtorisation in SmPC and Labelling have been added. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	29/11/2010	n/a	SPC, Labelling, PL	

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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