EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Docetaxel Mylan

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
IB/0006	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 is required to be submitted by the MAH	11/08/2014		SmPC	
IB/0004	Update of section 4.4 and 4.5 of the SmPC in order to add a warning and update the safety information on	19/03/2014	03/06/2014	SmPC	

[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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
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	interactions with CYP3A4 inhibitors further to the PRAC assessment of a signal. In addition, some inconsistencies have been rectified on the number and grade of alopecia adverse reactions in section 4.8 of the SmPC. Finally, minor linguistic amendments have been performed in BG, CS, DA,DE, ES, ET, FR, HU, HR, IT, LT, LV, MT, NO, PL, SK AND SV in order to align the annexes to the same language annexes of the originator Taxotere. 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 is required to be submitted by the MAH				
IB/0003/G	This was an application for a group of variations. To update section 4.4 to add warning on cystoid macular oedema based on the results of safety cumulative reviews conducted by the innovator's MAH and section 4.8 of the SmPC to include cystoid macular oedema and hyponatraemia in the list of adverse reactions following assessment by the CHMP for the originator product Taxotere. The Package Leaflet is updated accordingly. In addition the product information has been brought in line with the latest QRD version 9.0. Finally the contact details for the New Member State Croatia has been added to the list of local representatives in the Package Leaflet and the names of Bulgaria, Hungary, Greece and Cyprus have been corrected and written in their national languages.	18/11/2013	03/06/2014	SmPC and PL	

	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 is required to be submitted by the MAH 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 is required to be submitted by the MAH				
IB/0002	Update of the SmPC for Docetaxel Mylan following assessment of the same changes for the reference product, Taxotere. Sections 4.4 and 4.8 of the SPC are updated in order to add a warning related to respiratory disorders and to include interstitial pneumonitis, interstitial lung disease and pulmonary fibrosis as new adverse reactions observed the post-marketing setting following a relevant cumulative review of the originator product's safety database. The Package Leaflet is updated accordingly. The MAH has also taken the opportunity to update the Product Information according to the latest QRD template, version 9. 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	13/06/2013	03/06/2014	SmPC, Annex II and PL	

IB/0001	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	24/05/2012	n/a	SmPC, Labelling and PL	