EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Docetaxel Teva Pharma

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/0007/G	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	10/10/2013		SmPC and 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).

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	QRD version 9.0. Finally, the contact details for new Member State Croatia has been added to the list of local representatives in the Package Leaflet and the contact details for Hungary have been updated. This was an application for a group of variations. 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/0004	Update of the SmPC for Docetaxel Teva Pharma 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 MAH contact details in section 6 of the Package Leaflet. Furthermore, Labelling has been updated with the	12/06/2013		SmPC, Annex II, Labelling and PL	

	marketing authorisation numbers. In addition, minor linguistic amendments were carried out in the CS, FI, RO annexes. 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				
IAIN/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/05/2013	n/a		
IAIN/0003	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	22/06/2012	n/a	Annex II and PL	
IB/0002	Update of SmPC section 4.5 regarding interaction between docetaxel and ritonavir as well as update of SmPC section 4.8 regarding the risk of renal dysfunction, respiratory disorders, persisting alopecia and the frequency for leukaemia/MDS in the post-marketing section in accordance with the update for the reference product. The package leaflet has been updated accordingly. In addition, the MAH took the opportunity to update the PI in line with QRD version 8 as well as to introduce corrections to SmPC section 4.8 in line with the reference poduct. Furthermore, the contact details of the LoLR in the package leaflet have been updated 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	10/05/2012	n/a	SmPC, Annex II, Labelling and PL	

	product - Implementation of change(s) for which NO new additional data are submitted by the MAH				
IB/0001	Update of SmPC sections 4.4 and 4.8 following the final results of study TAX 316 in accordance with the update for the reference product Taxotere. In addition, the MAH took the opportunity to update the list of local representatives and Annex II. Furthermore, corrections have been introduced in the following languages: BG, CS, HU, PT, RO and DA. 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	03/02/2012	n/a	SmPC, Annex II and PL	