EMA/628087/2020

Docetaxel TEVA

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/0031	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	06/10/2020		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).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	the MAH				
IB/0030	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	08/04/2020	28/04/2020	SmPC and PL	
IB/0029	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	25/06/2019	28/04/2020	SmPC, Labelling and PL	
IB/0028	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	25/06/2018		SmPC, Labelling and PL	
IB/0027/G	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	16/01/2018		SmPC and PL	

	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/0026/G	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	05/10/2017		SmPC, Labelling and PL	
IB/0024/G	This was an application for a group of variations. B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	03/08/2016	n/a		

	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
IA/0023	A.7 - Administrative change - Deletion of manufacturing sites	25/04/2016	16/02/2017	Annex II and PL	
IB/0022	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	24/02/2016	16/02/2017	SmPC, Labelling and	

	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			PL	
T/0021	Transfer of Marketing Authorisation	04/11/2014	21/11/2014	SmPC, Labelling and PL	
PSUSA/1152/ 201311	Periodic Safety Update EU Single assessment - docetaxel	25/09/2014	n/a		PRAC Recommendation - maintenance
IB/0020	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	20/08/2014	21/11/2014	SmPC	
R/0013	Renewal of the marketing authorisation.	22/05/2014	14/07/2014	SmPC, Labelling and PL	
IB/0018	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	05/06/2014	n/a		
IB/0017	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	05/06/2014	n/a		
IB/0016	B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including	03/06/2014	n/a		

	replacement or addition)				
IB/0014	Update of section 4.4 and 4.5 of the SmPC in order to add a warning and update the safety information on 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. Furthermore, the contact details for the Maltese local representative 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 product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	19/03/2014	03/06/2014	SmPC and PL	
IB/0012/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 have been added to the list of local representatives in the Package Leaflet	10/10/2013	03/06/2014	SmPC and PL	

	and the contact details for Hungary 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 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/0009	Update of the SmPC for Docetaxel Teva following assessment of the same changes for the reference product, Taxotere. Sections 4.4 and 4.8 of the SmPC 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. 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	12/06/2013	03/06/2014	SmPC, Annex II and PL	

	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/0010	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/05/2013	n/a		
IAIN/0008	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	22/06/2012	11/09/2012	Annex II and PL	
IB/0007	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 as well as section 5.3 of the 80 mg strength 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 product - Implementation of change(s) for which NO new additional data are submitted by the MAH	10/05/2012	11/09/2012	SmPC, Annex II, Labelling and PL	

IB/0006	Update of SmPC sections 4.4, 4.8 and 5.1 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. Additionally, corrections have been introduced in the following languages: BG, CS, DE, FI, PT and RO. 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	11/09/2012	SmPC and PL	
IB/0005	To add a new therapeutic indication following the same changes for the reference product Taxotere (II-90 adopted in May 2010). In addition, few formatting changes have been carried out and the DDPS version number has been removed from Annex II. 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	08/02/2011	n/a	SmPC, Annex II and PL	To add a new therapeutic indication in order to reflect the changes to the innovator product Taxotere (II-90 adopted in May 2010). Few formatting changes have been carried out.
II/0002/G	This was an application for a group of variations. Changes relating to the Docetaxel Teva concentrate including: - change in the formulation of the Docetaxel	22/07/2010	26/08/2010	SmPC, Labelling and PL	

	concentrate, - change in the concentration of a single-dose total use parenteral product, - modification in the manufacturing process as a consequence of changes in the formulation of Docetaxel concentrate, - change of in-process test during the manufacturing of the fninished product, - extension of the shelf-life of Docetaxel concentrate. B.II.a.3.b.2 - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the product B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter as a result of a safety or quality issue B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.f.1.b.4 - Stability of FP - Extension of the shelf life of the finished product - Extension of the shelf-				

	life based on extrapolation of stability data not in accordance with ICH guidelines B.II.c.1.f - Change in the specification parameters and/or limits of an excipient - Addition or replacement (excluding biological or immunological product) of a specification parameter as a result of a safety or quality issue				
II/0001/G	This was an application for a group of variations. Changes relating to the solvent for solution for infusion for Docetaxel Teva drug product including: - changes in the formulation of solvent for solution for infusion, - changes in the manufacturing process of the finished product as a consequential of changes in the formulation, - extension of the shelf life of the solvent for solution for infusion. B.II.a.3.b.2 - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the product B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter	22/07/2010	26/08/2010	SmPC, Labelling and PL	

	B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.f.1.b.4 - Stability of FP - Extension of the shelf life of the finished product - Extension of the shelf-life based on extrapolation of stability data not in accordance with ICH guidelines				
II/0003/G	This was an application for a group of variations. Change in the batch size of the finished product Docetaxel Teva concentrate and solvent for solution for infusion. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change	22/07/2010	05/08/2010		

	relates to all other pharmaceutical forms manufactured by complex manufacturing processes				
IA/0004/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	27/05/2010	n/a	Annex II and PL	