Docetaxel Kabi

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/0038	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	26/09/2023		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).

IA/0037	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	02/06/2023	n/a		
IA/0036	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	21/03/2023	n/a		
IA/0035	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	11/01/2022	n/a		
IB/0034	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	17/09/2021	n/a		
IB/0033	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	26/02/2021	n/a		
IA/0032	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	14/01/2021	n/a		
IB/0031/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites C.I.2.a - Change in the SPC, Labelling or PL of a	12/10/2020	04/10/2021	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 is required to be submitted by the MAH				
IA/0030	B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	28/08/2020	n/a		
IB/0029	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	03/04/2020	n/a		
IB/0028	Update of sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC to include the treatment of patients with metastatic hormone-sensitive prostate cancer in combination with androgen-deprivation therapy (ADT), with or without prednisone or prednisolone. The Package Leaflet is updated accordingly. The changes have been implemented in line with the reference medicinal product. Additionally, MAH took the opportunity to correct minor editorial changes in SL, SK and RO Product Information. 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	31/01/2020	24/02/2020	SmPC and PL	

	new additional data is required to be submitted by the MAH				
IAIN/0027	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/12/2019	n/a		
II/0022	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	25/07/2019	n/a		
IB/0026/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	11/07/2019	n/a		
IB/0025	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	23/05/2019	28/06/2019	SmPC, Labelling and PL	
IA/0024/G	This was an application for a group of variations.	11/04/2019	n/a		

	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
IAIN/0023	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	21/03/2019	28/06/2019	Annex II and PL	
IB/0021	B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation	04/01/2019	n/a		
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	02/07/2018	28/06/2019	SmPC and PL	
T/0019	Transfer of Marketing Authorisation	18/04/2018	08/05/2018	SmPC,	

				Labelling and PL	
IB/0018/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 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	18/01/2018	08/05/2018	SmPC and PL	
IA/0017/G	This was an application for a group of variations. B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the	27/10/2017	n/a		

	relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer				
IB/0016	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	01/08/2017	08/05/2018	SmPC and PL	
R/0015	Renewal of the marketing authorisation.	15/12/2016	23/02/2017	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Docetaxel Kabi in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. Risk Management Plan (Version 1.0) is introduced.
IB/0014	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	12/07/2016	n/a		
IB/0013	B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	01/06/2016	n/a		
IB/0012	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	15/12/2015	12/12/2016	SmPC and PL	

IAIN/0011	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	16/07/2015	n/a		
IA/0010/G	This was an application for a group of variations. B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier 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	16/07/2015	n/a		
PSUSA/1152/ 201311	Periodic Safety Update EU Single assessment - docetaxel	25/09/2014	n/a		PRAC Recommendation - maintenance
IB/0009	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	17/07/2014	03/07/2015	SmPC	
IB/0007	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	19/03/2014	22/05/2014	SmPC	

	4.8 of the SmPC. 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/0006/G	This was an application for a group of variations. Update of the SmPC following the 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. In addition, Annex II is being brought in line with QRD template version 8.3. Furthermore, minor linguistic and typographical errors were rectified for the German, Hungarian and Lithuanian 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	17/10/2013	22/05/2014	SmPC and PL	

	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/0005	Update of the SmPC following the 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. In addition, Annex II is being brought in line with QRD template version 8.3. Furthermore, minor linguistic and typographical errors were rectified for the German, Hungarian and Lithuanian 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	29/05/2013	22/05/2014	SmPC, Annex II and PL	

II/0001/G	This was an application for a group of variations. To change the manufacturing process of the active substance. The storage condition for Docetaxel anhydrous has been revised to comply with the Ph.Eur. To tight some specifications limits. To add new specification parameters to the specification with its corresponding test methods. To delete of non-significant specification parameters (UV and melting point). B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of	15/11/2012	15/11/2012		

	an obsolete parameter)				
II/0002	Addition of pack size of 20 mg/1 ml to Docetaxel Kabi 20 mg/ml Concentrate for Solution for Infusion. B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, and biological/immunological multidose parenteral medicinal products	20/09/2012	29/10/2012	SmPC, Annex II, Labelling and PL	