



## Docetaxel Accord

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
IA/0058	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)	12/09/2023	n/a		

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



IB/0057	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	12/09/2023		SmPC and PL	
IB/0056	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	17/08/2023	n/a		
IA/0055	B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)	12/06/2023	n/a		
IB/0054	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	09/03/2023		SmPC and PL	
IA/0053	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)	13/01/2023	n/a		
IA/0052	B.III.1.a.4 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material)	09/12/2022	n/a		
IA/0051	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished	14/06/2022	n/a		

	product formulation - Change that does not affect the product information				
IA/0050	A.7 - Administrative change - Deletion of manufacturing sites	16/12/2021	28/11/2022	Annex II and PL	
IAIN/0049/G	This was an application for a group of variations.  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 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	31/08/2021	n/a		
IB/0048	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	12/10/2020	04/10/2021	SmPC and PL	
IB/0047	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	17/01/2020	21/02/2020	SmPC and PL	

IA/0046	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	09/12/2019	n/a		
IA/0045/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	15/07/2019	n/a		
IB/0044	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	21/02/2020	SmPC and PL	
IAIN/0043/G	This was an application for a group of variations.  A.7 - Administrative change - Deletion of manufacturing sites  B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	06/05/2019	n/a		
IAIN/0042/G	This was an application for a group of variations.	05/03/2019	n/a		

	<p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>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</p> <p>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</p> <p>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</p>				
T/0041	Transfer of Marketing Authorisation	11/01/2019	01/03/2019	SmPC, Labelling and PL	
IAIN/0040/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>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</p>	12/10/2018	01/03/2019	Annex II and PL	

IB/0039/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site</p> <p>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</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p>	28/09/2018	n/a		
IA/0037/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the</p>	20/07/2018	n/a		

	<p>relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer</p> <p>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</p> <p>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</p> <p>B.III.1.a.4 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material)</p>				
IB/0038	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	19/07/2018	n/a		
IB/0036	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	18/06/2018	02/07/2018	SmPC and PL	
IB/0035	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	17/01/2018	02/07/2018	SmPC and PL	

	new additional data is required to be submitted by the MAH				
IB/0034/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p>	21/12/2017	02/07/2018	SmPC and PL	
IA/0033	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)	29/11/2017	n/a		
IB/0032	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	28/07/2017	02/07/2018	SmPC and PL	
R/0030	Renewal of the marketing authorisation.	15/12/2016	23/02/2017	SmPC, Annex	Based on the review of data on quality, safety and efficacy,



				II, Labelling and PL	the CHMP considered that the benefit-risk balance of Docetaxel Accord in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IAIN/0031	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	16/12/2016	n/a		
IA/0029/G	This was an application for a group of variations.  B.II.e.3.b - Change in test procedure for the immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition)  B.III.2.b - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	19/05/2016	n/a		
II/0026	B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes	10/03/2016	n/a		
IA/0028	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)	22/02/2016	n/a		

IB/0027	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	28/01/2016	27/01/2017	SmPC, Labelling and PL	
IAIN/0025	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	14/07/2015	n/a		
IA/0024	B.III.1.a.4 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material)	29/05/2015	n/a		
IAIN/0023	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	13/05/2015	n/a		
IB/0021/G	This was an application for a group of variations.  B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	07/11/2014	n/a		
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	09/07/2014	03/07/2015	SmPC	
IB/0019/G	This was an application for a group of variations.  B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF  B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS	12/05/2014	n/a		
IAIN/0018	B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	11/04/2014	n/a		
IB/0015	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 Product Information was brought in line with the latest QRD	19/03/2014	16/05/2014	SmPC	

	<p>template version 9.0.</p> <p>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</p>				
IA/0016	<p>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</p>	07/03/2014	n/a		
IB/0012/G	<p>This was an application for a group of variations.</p> <p>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.</p> <p>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</p>	20/11/2013	16/05/2014	SmPC and PL	

	<p>new additional data is required to be submitted by the MAH</p> <p>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</p>				
IAIN/0011	<p>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</p>	30/08/2013	n/a		
II/0007	<p>To add an alternative batch size of the finished product.</p> <p>B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes</p>	27/06/2013	n/a		
IB/0010	<p>Update of the SmPC for Docetaxel Accord 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.</p>	14/06/2013	16/05/2014	SmPC, Annex II and PL	

	<p>The Package Leaflet is updated accordingly. Annex II was also updated according to QRD template version 8.3.</p> <p>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</p>				
IB/0009	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	12/06/2013	n/a		
IB/0005/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>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</p>	22/03/2013	n/a		
IB/0006/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.z - Change in the manufacturing process of</p>	20/02/2013	n/a		

	<p>the finished product - Other variation</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation</p> <p>B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation</p>				
IB/0008	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	11/02/2013	n/a		
IB/0003/G	<p>This was an application for a group of variations.</p> <p>B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF</p> <p>B.III.2.a.1 - Change of specification('s) of a former non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS</p>	21/11/2012	n/a		
IB/0002	<p>To extend the shelf-life of the finished product from 15 to 24 months.</p> <p>B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)</p>	18/09/2012	29/10/2012	SmPC	
IB/0001	B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	22/08/2012	n/a		

