



Capecitabine 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
IAIN/0036	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	24/02/2021		SmPC and PL	
A31/0031	Pursuant to Article 31 of Directive 2001/83/EC, France requested on 13 March 2019 the opinion of the European Medicines Agency to assess the need to take	30/04/2020	03/07/2020	SmPC and PL	Please refer to the assessment report: Capecitabine Teva EMEA/H/A-31/1481/C/002362/0031

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).



	<p>action at EU level regarding the detection of DPD deficient patients (especially through genotyping and/or phenotyping) in patients treated with fluorouracil and related substances (capecitabine, tegafur and flucytosine). The Agency was requested to assess the impact thereof on the benefit-risk balance of fluorouracil and related substances containing products and to give its opinion on whether the marketing authorisation of these products should be maintained, varied, suspended or revoked.</p>				
IB/0034	<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>	05/06/2020	17/07/2020	SmPC, Annex II, Labelling and PL	
IAIN/0035	<p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p>	02/06/2020	n/a		
IB/0033	<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>	25/09/2019	17/10/2019	SmPC and PL	

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	06/06/2019	17/10/2019	SmPC and PL	
IB/0029/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	06/11/2018	n/a		
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	18/10/2018	17/10/2019	SmPC, Labelling and PL	
IAIN/0028/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.	02/10/2018	n/a		

	Eur. Monograph - Updated certificate from an already approved manufacturer				
N/0027	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/02/2018	17/10/2019	PL	
R/0025	Renewal of the marketing authorisation.	10/11/2016	09/01/2017	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 Capecitabine Teva in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0026	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	16/09/2016	09/01/2017	SmPC, Labelling and PL	
IB/0023	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	11/08/2016	n/a		
IA/0024/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	01/08/2016	n/a		
IB/0022/G	This was an application for a group of variations.	20/04/2016	n/a		

	<p>B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data</p> <p>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</p> <p>B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation</p> <p>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</p>				
IB/0021	<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>	26/02/2016	31/03/2016	SmPC and PL	
IA/0020/G	<p>This was an application for a group of variations.</p> <p>A.7 - Administrative change - Deletion of manufacturing sites</p> <p>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</p>	05/08/2015	n/a		

	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IAIN/0019/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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	24/06/2015	n/a		
IB/0018	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	19/05/2015	31/03/2016	SmPC, Labelling and PL	
T/0017	Transfer of Marketing Authorisation from Teva Pharma B.V. (Utrecht) to Teva B.V. (Haarlem). Transfer of Marketing Authorisation	04/11/2014	21/11/2014	SmPC, Labelling and PL	
IAIN/0016/G	This was an application for a group of variations. 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.c.2.a - Change in test procedure for an excipient -	01/08/2014	n/a		

	<p>Minor changes to an approved test procedure</p> <p>B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product</p>				
IA/0015/G	<p>This was an application for a group of variations.</p> <p>B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size</p> <p>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits</p> <p>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits</p>	17/06/2014	n/a		
IB/0014/G	<p>This was an application for a group of variations.</p> <p>B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation</p> <p>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</p>	15/04/2014	n/a		
IB/0013/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</p>	03/04/2014	21/11/2014	SmPC and PL	

	<p>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> <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>				
IA/0012/G	<p>This was an application for a group of variations.</p> <p>A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient</p> <p>A.7 - Administrative change - Deletion of</p>	28/11/2013	n/a		

	<p>manufacturing sites</p> <p>B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits</p>				
IAIN/0011	<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>	14/10/2013	20/02/2014	Annex II and PL	
II/0002/G	<p>This was an application for a group of variations.</p> <ul style="list-style-type: none"> - to introduce a new active substance manufacturer and - to introduce a minor change in the manufacturing process of the finished product when active substance from the new active substance manufacturer is used. <p>B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is supported by an ASMF</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions</p>	19/09/2013	n/a		
IB/0010	<p>C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following</p>	11/09/2013	20/02/2014	SmPC, Annex II, Labelling	

	assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH			and PL	
IB/0006/G	<p>This was an application for a group of variations.</p> <p>B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products</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.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions</p>	05/08/2013	20/02/2014	Annex II and PL	
IB/0008/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>B.II.c.2.d - Change in test procedure for an excipient - Other changes to a test procedure (including</p>	29/07/2013	n/a		

	<p>replacement or addition)</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p>				
IB/0007/G	<p>This was an application for a group of variations.</p> <p>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate</p> <p>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate</p> <p>B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p>	21/06/2013	n/a		
IA/0009/G	<p>This was an application for a group of variations.</p> <p>B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms</p> <p>B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding</p>	03/06/2013	n/a		

	test method				
IAIN/0005	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/05/2013	n/a		
IAIN/0004	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/04/2013	n/a		
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	11/04/2013	n/a		
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	06/03/2013	20/02/2014	SmPC and PL	