



## Temozolomide Sandoz

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
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	24/05/2022		SmPC, Labelling and PL	

<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).



IA/0035	A.7 - Administrative change - Deletion of manufacturing sites	02/03/2021	n/a		
IB/0034	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	06/07/2020	30/09/2020	SmPC, Annex II, Labelling and PL	
IAIN/0033	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/09/2019	30/09/2020	SmPC	
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	19/06/2018	06/06/2019	SmPC, Labelling and PL	
IB/0031	B.II.z - Quality change - Finished product - Other variation	18/05/2018	06/07/2018	SmPC and PL	
IA/0030	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	22/02/2018	n/a		
IB/0029	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	17/07/2017	06/07/2018	SmPC, Labelling and PL	

IAIN/0028	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	20/01/2017	n/a		
IB/0027/G	This was an application for a group of variations.  B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	11/10/2016	n/a		
IA/0026	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	07/10/2016	n/a		
IAIN/0025/G	This was an application for a group of variations.  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) B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	23/03/2016	n/a		

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IB/0024	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	14/07/2015	15/07/2016	SmPC and PL	
T/0023	Transfer of Marketing Authorisation	18/02/2015	16/03/2015	SmPC, Labelling and PL	
IA/0022	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)	18/12/2014	n/a		
R/0020	Renewal of the marketing authorisation.	25/09/2014	19/11/2014	SmPC and PL	Based on the review of the available information, the CHMP is of the opinion that the quality, the safety and the efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considers the benefit/risk profile of Temozolomide Sandoz continues to be favourable. The CHMP is also of the opinion that the renewal can be granted with unlimited validity.
IB/0021	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	19/08/2014	19/11/2014	SmPC and PL	

II/0019	<p>Broaden the limit for one impurity in the finished product.</p> <p>B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range</p>	24/07/2014	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	12/02/2014	19/11/2014	SmPC, Annex II, Labelling and PL	
IB/0017	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	10/04/2013	22/01/2014	SmPC and PL	
IA/0016	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	07/02/2013	n/a		
IB/0015	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)	19/12/2012	22/01/2014	SmPC	
IB/0014	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	05/09/2012	25/10/2012	SmPC, Labelling and PL	

	product - Implementation of change(s) for which NO new additional data are submitted by the MAH				
IB/0012	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)	14/06/2012	25/10/2012	SmPC	
IB/0011/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.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-</p>	18/04/2012	15/06/2012	SmPC, Labelling and PL	

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	<p>solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p> <p>B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms</p>				
IB/0010	<p>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</p>	12/01/2012	n/a		

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IB/0008	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	22/11/2011	15/06/2012	SmPC	
IB/0009	C.I.2.z - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Other variation	15/11/2011	15/06/2012	SmPC, Annex II, Labelling and PL	
II/0006	To increase the shelf life specification limit of the finished product for some impurities.  B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	21/07/2011	21/07/2011		
IA/0007	C.I.9.i - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	20/07/2011	n/a		
II/0005/G	This was an application for a group of variations.  To reduce the amount of desiccant and to replace the desiccant disc with a desiccant pouch. To add the special storage condition "Do not store above 25°C". To reduce the shelf-life from 2 years to 1 year. To change the medicinal product's release and shelf-	14/04/2011	23/06/2011	SmPC, Annex II, Labelling and PL	



	<p>life specification</p> <p>To delete all HDPE bottle presentations (EU/1/10/617/003, 004, 007, 008, 011, 012, 015, 016, 019, 020, 023, 024).</p> <p>In addition, the MAH has taken the opportunity to delete the version number of the DDPS in Annex II.</p> <p>B.II.e.1.z - Change in immediate packaging of the finished product - Other variation</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p>				
IB/0004/G	<p>This was an application for a group of variations.</p> <p>B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place</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>	05/08/2010	n/a		
N/0002	<p>Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)</p>	05/07/2010	n/a	PL	
IA/0001	<p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p>	18/06/2010	n/a		

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