



## Temozolomide SUN

### 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	15/03/2022		SmPC 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).



N/0035	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/12/2021		PL	
IA/0034	A.7 - Administrative change - Deletion of manufacturing sites	09/11/2021	n/a		
IB/0033	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	10/07/2020	16/11/2020	SmPC and PL	
N/0032	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/03/2020	16/11/2020	PL	
IAIN/0031	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/09/2019	16/11/2020	SmPC, Annex II, Labelling and PL	
IB/0029/G	This was an application for a group of variations.  B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF 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	12/04/2019	n/a		

	size				
N/0030	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/04/2019	25/07/2019	Labelling	
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/10/2018	25/07/2019	PL	
IA/0027/G	<p>This was an application for a group of variations.</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p> <p>B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)</p>	03/08/2018	25/07/2019	SmPC, Labelling and PL	

	product - Deletion of a pack size(s) B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)				
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	14/06/2018	30/07/2018	SmPC, Labelling and PL	
IA/0025	B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits	27/09/2017	n/a		
IAIN/0024	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	14/07/2017	30/07/2018	SmPC and PL	
IAIN/0023	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	18/01/2017	n/a		
N/0022	Update of the package leaflet with revised contact details of the local representatives for Spain and Italy.  Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/07/2016	30/07/2018	PL	
R/0019	Renewal of the marketing authorisation.	25/02/2016	21/04/2016	SmPC,	Based on the review of data on quality, safety and efficacy,

				Labelling and PL	the CHMP considered that the benefit-risk balance of Temozolomide SUN in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0021	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	13/04/2016	n/a		
IB/0020/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>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.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.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits</p> <p>B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits</p> <p>B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits</p>	11/03/2016	n/a		

	B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits 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)				
IAIN/0018	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	24/09/2015	n/a		
IA/0017	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	16/09/2015	n/a		
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	22/06/2015	28/07/2015	SmPC and PL	
IB/0015	B.II.b.5.f - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue	16/06/2015	n/a		
IB/0014	B.II.e.6.b - Change in any part of the (primary)	16/12/2014	n/a		

	packaging material not in contact with the finished product formulation - Change that does not affect the product information				
IB/0013	<p>Update of section 4.8 of the SmPC to include the calculated frequency of hepatic-related disorders following adoption of the same changes for the reference product. Section 4 of the Package Leaflet was updated accordingly.</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>	14/08/2014	28/07/2015	SmPC and PL	
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)	16/07/2014	28/07/2015	SmPC	
IB/0010/G	<p>This was an application for a group of variations.</p> <p>B.I.c.z - Container closure system of the AS - Other variation</p> <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>	16/07/2014	n/a		
IAIN/0011	B.II.b.1.a - Replacement or addition of a	23/06/2014	n/a		

	manufacturing site for the FP - Secondary packaging site				
IAIN/0008	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	12/02/2014	21/03/2014	SmPC and PL	
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	06/02/2014	21/03/2014	SmPC and PL	
IB/0007	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)	06/02/2014	21/03/2014	SmPC	
IAIN/0006	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	26/11/2013	n/a		
II/0005	To change the approved specification limits for the active substance.  B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	21/11/2013	n/a		



IB/0004	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	20/03/2013	21/03/2014	SmPC, Annex II and PL	
IAIN/0003/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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	14/01/2013	n/a		
IB/0002/G	This was an application for a group of variations.  B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g.	19/09/2012	25/10/2012	SmPC, Labelling and PL	



	tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
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	05/09/2012	25/10/2012	SmPC, Annex II, Labelling and PL	