EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Temozolomide Hexal

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/0037	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	

[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).

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IA/0036	A.7 - Administrative change - Deletion of manufacturing sites	02/03/2021	n/a		
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 new additional data is required to be submitted by the MAH	06/07/2020	30/09/2020	SmPC, Annex II, Labelling and PL	
IAIN/0034	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	27/09/2019	30/09/2020	SmPC	
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	19/06/2018	06/06/2019	SmPC, Labelling and PL	
IB/0032	B.II.z - Quality change - Finished product - Other variation	18/05/2018	06/07/2018	SmPC and PL	
IA/0031	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/0030	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/0029	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/0028/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/0027	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		
IA/0026	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)	23/03/2016	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	14/07/2015	15/07/2016	SmPC and PL	

	the MAH				
IA/0024	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/0022	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 Hexal continues to be favourable. The CHMP is also of the opinion that the renewal can be granted with unlimited validity.
IB/0023	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. In addition, the MAH took the opportunity to align the PI to the reference product, introduce minor editorial changes, add missing QRD updates. 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	08/08/2014	19/11/2014	SmPC and PL	

II/0020	Broaden the limit for one impurity in the finished product. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	24/07/2014	n/a		
IAIN/0021/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. 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. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	08/05/2014	19/11/2014	SmPC, Labelling and PL	
IAIN/0019/G	This was an application for a group of variations.	07/05/2014	19/11/2014	SmPC,	

	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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			Labelling and PL	
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	13/03/2014	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	13/12/2013	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	13/12/2013	SmPC	
IB/0014	C.I.2.a - Change in the SPC, Labelling or PL of a	05/09/2012	25/10/2012	SmPC,	

	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			Labelling 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)	14/06/2012	25/10/2012	SmPC	
IB/0011/G	This was an application for a group of variations. 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 B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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 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 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	23/03/2012	15/06/2012	SmPC, Labelling and PL	

	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 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 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 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 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 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 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 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 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				
IB/0010	B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological	03/02/2012	n/a		

	product) of a specification parameter as a result of a safety or quality issue				
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	15/12/2011	15/06/2012	SmPC, Annex II, Labelling and PL	
IB/0007	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	
II/0005	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/0006	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/0004/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".	14/04/2011	23/06/2011	SmPC, Annex II, Labelling and PL	

	To reduce the shelf-life from 2 years to 1 year. To change the medicinal product's release and shelf-life specification To delete all HDPE bottle presentations (EU/1/10/616/003, 004, 007, 008, 011, 012, 015, 016, 019, 020, 023, 024). In addition, the MAH has taken the opportunity to delete the version number of the DDPS in Annex II. B.II.e.1.z - Change in immediate packaging of the finished product - Other variation B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)				
IB/0003/G	This was an application for a group of variations. 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 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	05/08/2010	n/a		
IA/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	18/06/2010	n/a		