Temozolomide Accord

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
IA/0067	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	16/08/2024	n/a		
N/0066	Minor change in labelling or package leaflet not	14/08/2024		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).

	connected with the SPC (Art. 61.3 Notification)				
IA/0065	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	12/01/2024	n/a		
IA/0064	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)	17/11/2023	n/a		
IB/0063/G	This was an application for a group of variations. 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 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 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	26/06/2023	05/07/2024	SmPC and PL	

IA/0062/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.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	31/01/2023	n/a		
IA/0061/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.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	24/03/2022	n/a		
IB/0060	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	18/03/2022	06/03/2023	SmPC and PL	
IAIN/0059	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)	14/12/2021	n/a		

IA/0058/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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 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 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	13/12/2021	04/02/2022	Annex II and PL	
IA/0057/G	This was an application for a group of variations. 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 A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of	23/07/2021	n/a		

	manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				
IB/0056	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/07/2021	04/02/2022	SmPC and PL	
IAIN/0055	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	27/01/2021	04/02/2022	Annex II and PL	
IB/0054/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.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	23/09/2020	n/a		
IAIN/0053	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	28/08/2020	n/a		

IB/0052	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	15/06/2020	19/10/2020	SmPC and PL	
IAIN/0051	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	17/04/2020	n/a		
IA/0050	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	26/02/2020	n/a		
IAIN/0049	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	27/01/2020	n/a		
IAIN/0048	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	20/09/2019	19/10/2020	SmPC	
IA/0047	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	01/07/2019	n/a		
IAIN/0046/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	05/03/2019	n/a		

	site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site				
T/0045	Transfer of Marketing Authorisation	01/02/2019	25/02/2019	SmPC, Labelling and PL	
IAIN/0044	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	27/09/2018	25/02/2019	Annex II and PL	
IB/0043	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	23/05/2018	29/06/2018	SmPC, Labelling and PL	
IAIN/0042	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	22/01/2018	n/a		
IB/0041	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/07/2017	29/06/2018	SmPC and PL	
IAIN/0040	B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply	18/01/2017	n/a		

	with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS				
IAIN/0039	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/12/2016	n/a		
IA/0038	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)	29/09/2016	n/a		
IB/0037/G	This was an application for a group of variations. B.II.a.3.b.1 - Changes in the composition (excipients) of the finished product - Other excipients - Any minor adjustment of the quantitative composition of the finished product with respect to excipients B.II.a.3.z - Changes in the composition (excipients) of the finished product - Other variation	27/06/2016	22/05/2017	SmPC and PL	
IA/0036	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	17/02/2016	n/a		
II/0035	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	22/10/2015	n/a		
IB/0033	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	14/07/2015	02/06/2016	SmPC and PL	

	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				
IAIN/0034	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	26/06/2015	02/06/2016	Annex II and PL	
IB/0031/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.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms 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	12/06/2015	02/06/2016	SmPC, Labelling and PL	

	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 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 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				
IAIN/0032/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.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) 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 B.II.e.7.b - Change in supplier of packaging	05/06/2015	n/a		

	components or devices (when mentioned in the dossier) - Replacement or addition of a supplier 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				
T/0029	Transfer of Marketing Authorisation	10/04/2015	27/05/2015	SmPC, Labelling and PL	
IAIN/0030/G	This was an application for a group of variations. A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs 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	18/03/2015	27/05/2015	SmPC, Labelling and PL	
R/0026	Renewal of the marketing authorisation.	23/10/2014	12/01/2015	SmPC, Annex II, Labelling 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 Hospira continues to be favourable. The CHMP is also of the opinion that the renewal can be granted with unlimited validity.
IG/0477	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	03/09/2014	n/a		

	PSMF location				
IB/0027	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. 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	14/08/2014	12/01/2015	SmPC and PL	
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 the MAH	12/02/2014	28/02/2014	SmPC and PL	
IA/0024/G	This was an application for a group of variations. 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 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	17/12/2013	n/a		

	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 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				
IA/0022/G	This was an application for a group of variations. 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 A.7 - Administrative change - Deletion of manufacturing sites	11/12/2013	n/a		
IG/0382	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	02/12/2013	n/a		
IA/0021	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	14/08/2013	n/a		
IG/0317	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/07/2013	n/a		
IAIN/0019	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	03/06/2013	n/a		

	site				
IG/0286	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/04/2013	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 are submitted by the MAH	04/04/2013	28/02/2014	SmPC and PL	
IA/0017	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	20/03/2013	n/a		
IA/0015	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	20/12/2012	n/a		
IB/0014	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)	21/11/2012	28/02/2014	SmPC	
IB/0013	In line with the CHMP adoption of variations to the Marketing Authorisation of the Originator Product Temodal (EMEA/H/C222/II/59) on 24.05.2012 the Product Information (PI) for Temozolomide Hospira was updated with changes to the SmPC in order to add a warning regarding the risk of myelosuppression including prolonged pancytopenia following the assessment of PSUR. The package leaflet was improved and brought in line accordingly.	09/10/2012	25/10/2012	SmPC, Annex II, Labelling and PL	

	In addition, the Spanish PI translation was brought in line with the approved Spanish text of the originator product. Furthermore, the PI is brought in line with the latest QRD template, version 8. 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				
N/0012	To combine the package leaflets as did the reference product and to add the list of the local representatives in annex IIIB. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/08/2012	25/10/2012	PL	
IB/0010	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)	22/06/2012	25/10/2012	SmPC	
IAIN/0011	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/06/2012	n/a		
IAIN/0009/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance	20/04/2012	n/a		

	system as described in the DDPS - Change in the QPPV C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system				
IB/0008	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	10/01/2012	n/a		
IB/0006	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	25/05/2012	SmPC	
IB/0007	to update section 4.8 of the SmPC for Temozolomide Hospira Hard Capsules to include information on the possible risk of hepatotoxicity associated with Temozolomidel identified following a cumulative review. The PL has been updated accordingly. 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	21/10/2011	n/a	SmPC, Labelling and PL	to update section 4.8 of the SmPC to include information on the possible risk of hepatotoxicity associated with Temozolomidel identified following a cumulative review. The PL has been updated accordingly. Furthermore, additional editorial changes have been made to bring the SmPC and PL in line with the innovator. Additionally, typographical errors in DA, SV, HU, PT and FI annexes were corrected.

IB/0005/G	This was an application for a group of variations. B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation 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.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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 B.I.d.1.a.1 - Stability of AS - Change in the re-test period/storage period - Reduction	08/09/2011	n/a		
II/0004	To increase the shelf-life specification limit in the finished product for Impurity A and for the Total Impurities. B.II.d.1.f - Change in the specification parameters and/or limits of the finished product - Deletion of a specification parameter which may have a significant effect on the overall quality of the finished product	21/07/2011	21/07/2011		
II/0001/G	This was an application for a group of variations.	14/04/2011	27/05/2011	SmPC, Annex II, Labelling	

	To reduce the amount of desiccant and to replace the desiccant disc with a 0.25 g desiccant pouch. To restrict the special storage condition to "Do not store above 25°C". To reduce the shelf-life from 2 years to 1 year for all capsules strengths To change the medicinal product's release and shelf-life specification To delete all HDPE bottle presentations This variation is linked to the quality defect with broken capsules and therefore submitted as a Type II variation. The MAH has identified the desiccant to be the root cause. In addition, the MAH has taken the opportunity to delete the version number of the DDPS in Annex II. B.II.e.1.b.2 - Change in immediate packaging of the finished product - Type of container - Sterile medicinal products and biological/immunological medicinal products B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)			and PL	
IA/0003	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	01/12/2010	n/a		
IA/0002	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	03/11/2010	n/a		