Topotecan Hospira

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/0050	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	12/12/2024		SmPC 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).

IAIN/0049	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	25/07/2024	n/a		
IB/0048/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 A.6 - Administrative change - Change in ATC Code/ATC Vet Code A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	01/08/2022	04/08/2023	SmPC, Annex II, Labelling and PL	
IB/0045	B.II.f.1.e - Stability of FP - Change to an approved stability protocol	07/03/2022	n/a		
N/0047	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/03/2022	04/08/2023	PL	
IA/0046	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)	14/02/2022	n/a		

IB/0044/G	This was an application for a group of variations. B.II.z - Quality change - Finished product - Other variation B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	12/11/2021	n/a		
N/0043	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/10/2021	04/08/2023	PL	
IA/0042	A.7 - Administrative change - Deletion of manufacturing sites	09/02/2021	22/10/2021	Annex II and PL	
PSUSA/2997/ 202005	Periodic Safety Update EU Single assessment - topotecan	14/01/2021	n/a		PRAC Recommendation - maintenance
IB/0040	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	04/01/2021	22/10/2021	SmPC, Annex II, Labelling and PL	
IA/0041	A.7 - Administrative change - Deletion of manufacturing sites	22/10/2020	22/10/2021	Annex II and PL	

N/0038	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/10/2020	22/10/2021	PL	
N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/12/2019	22/10/2021	PL	
N/0036	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/04/2019	05/12/2019	PL	
IAIN/0035/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	12/12/2018	05/12/2019	Annex II and PL	
N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/10/2018	05/12/2019	PL	
T/0033	Transfer of Marketing Authorisation	06/08/2018	20/09/2018	SmPC, Labelling 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	13/04/2018	20/09/2018	SmPC, Annex II and PL	

	the MAH				
N/0031	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/11/2017	20/09/2018	PL	
N/0030	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/02/2017	20/09/2018	Labelling and PL	
IB/0029/G	This was an application for a group of variations. 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 B.I.d.1.b.3 - Stability of AS - Change in the storage conditions - Change in storage conditions of the AS	09/01/2017	n/a		
N/0028	Update of the package leaflet with revised contact details of the local representatives for Belgium, Germany, Spain, Ireland, Luxembourg, the Netherlands, Austria and Portugal. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/06/2016	14/11/2016	PL	
IG/0693	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/06/2016	n/a		
PSUSA/2997/ 201505	Periodic Safety Update EU Single assessment - topotecan	14/01/2016	n/a		PRAC Recommendation - maintenance

IG/0645	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	17/12/2015	n/a		
IAIN/0024/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH 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	24/11/2015	14/11/2016	SmPC, Annex II, Labelling and PL	
IB/0022/G	This was an application for a group of variations. B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits B.II.e.2.a - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Tightening of specification limits 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 test method 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	13/08/2015	n/a		

	test method B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information				
R/0019	Renewal of the marketing authorisation.	26/03/2015	28/05/2015		
IG/0555	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	22/05/2015	n/a		
IB/0020	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	19/12/2014	28/05/2015	SmPC, Labelling and PL	

IAIN/0018	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	03/10/2014	n/a		
IAIN/0017/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) A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site A.7 - Administrative change - Deletion of manufacturing sites	04/09/2014	n/a		
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 PSMF location	03/09/2014	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		
IAIN/0013	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	23/07/2013	27/06/2014	Annex II and PL	

IG/0317	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/07/2013	n/a		
IAIN/0011	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	23/04/2013	n/a		
IG/0286	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	12/04/2013	n/a		
N/0009	Update of contact details of the local representatives in the package leaflet. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/10/2012	29/10/2012	PL	
IAIN/0008/G	This was an application for a group of variations. B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	25/06/2012	n/a		
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)	07/06/2012	29/10/2012	SmPC	

IAIN/0006/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance 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.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD 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	18/04/2012	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	11/11/2011	15/05/2012	SmPC and PL	To align the Topotecan Hospira PI with that of the Hycamtin reference product, by inserting details of the ovarian cancer indication currently approved in the innovator text. Minor typographical/administrative changes have also been made to some texts to align with that of the innovator.
IB/0005	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)	25/10/2011	n/a	SmPC	

IB/0003	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	25/02/2011	n/a	SmPC and PL	The MAH applied to bring the SmPC in line to reflect the changes made to the parent product Hycamtin.
IA/0002	B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place	09/09/2010	n/a		
IA/0001	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	06/09/2010	n/a		