Topotecan Teva

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/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 product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	22/06/2018		SmPC, Labelling and PL	
IA/0013	A.7 - Administrative change - Deletion of manufacturing sites	14/12/2017		Annex II 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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IB/0012/G	This was an application for a group of variations. B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method 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	15/07/2016	n/a		
PSUSA/2997/ 201505	Periodic Safety Update EU Single assessment - topotecan	14/01/2016	n/a		PRAC Recommendation - maintenance
IB/0010	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	29/01/2015	11/03/2016	SmPC, Annex II and PL	
IB/0009	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	12/12/2014	n/a		
T/0008	Transfer of Marketing Authorisation fom Teva Pharma B.V. (Utrecht) and Teva B.V (Haarlem). Transfer of Marketing Authorisation	12/11/2014	28/11/2014	Annex II, Labelling and PL	

R/0007	Renewal of the marketing authorisation.	25/04/2014	19/06/2014	SmPC, Labelling and PL	Based on the CHMP review of data on quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, the CHMP considers by consensus that the risk-benefit balance of Topotecan Teva in the treatment of metastatic carcinoma of the ovary, relapsed small cell lung cancer [SCLC] and carcinoma of the cervix remains favourable and therefore recommends the renewal of the marketing authorisation with unlimited validity.
N/0006	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/09/2013	19/06/2014	PL	
N/0005	Update the contact details for the MAH representatives in the Package Leaflet and for the Latvian translation, to bring the INN in line with the information on the Labeling. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/02/2013	19/06/2014	PL	
IAIN/0004	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	05/06/2012	25/10/2012	Annex II and PL	
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	11/02/2011	n/a	SmPC, Annex II and PL	The MAH applied to bring the SmPC in line to reflect the changes made to the parent product Hycamtin. Few minor formatting changes have been added.
IB/0002	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other	07/07/2010	n/a	SmPC	

	variation				
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/12/2009	n/a	Labelling and PL	