EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Topotecan Actavis

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/0013	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	19/01/2015		SmPC, Labelling and PL	
N/0012	Minor change in labelling or package leaflet, not connected with the SPC (Art. 61.3 Notification)	13/08/2014		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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R/0011	Renewal of the marketing authorisation.	20/03/2014	06/06/2014	SmPC, Annex II, Labelling and PL	No significant new information on efficacy and effectiveness has been submitted with the renewal dossier. The efficacy profile is not changed by the presented data. The most important risk of Topotecan Actavis according to the presented data is myelotoxicity, which is a well-known risk for the substance. The most common side effects with the reference medicinal product, Hycamtin, are neutropenia, febrile neutropenia, thrombocytopenia, anaemia, leucopenia, nausea, vomiting and diarrhoea (all of which may be severe), constipation, abdominal pain, alopecia (hair loss), anorexia (loss of appetite, which may be severe), pyrexia, asthenia and fatigue. Neutropenia as a side-effect of Hycamtin can lead to neutropenic colitis, causing severe abdominal pain, fever and possibly diarrhoea, and which may need hospital treatment. All these risks are adequately communicated in the SmPC. No new safety information has been revealed at this stage. From the review of the available information on accumulated experience in terms of safety/efficacy data, it can be concluded that the risk-benefit balance of Topotecan Actavis when used as stated in the Summary of Product Characteristics remains favourable. Routine pharmacovigilance and risk minimisation measures are considered appropriate to minimize the risks associated with the medicinal product. The renewal can be granted with unlimited validity. The next periodic safety update report will be submitted in August 2015.
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/10/2013	06/06/2014	PL	

IB/0009	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the currently approved batch size	16/01/2012	n/a		
IB/0007/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes 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)	21/09/2011	21/09/2011	SmPC, Labelling and PL	
IB/0003		25/07/2011	n/a	SmPC, Annex II and PL	
IB/0004	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	07/07/2011	n/a		
N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/12/2009	n/a	PL	