EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Capecitabine SUN

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/0007	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	07/05/2015		SmPC	
IB/0006/G	This was an application for a group of variations.	25/03/2015	n/a		

[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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	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorised B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation 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				
IA/0005	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 originally approved batch size	02/07/2014	n/a		
IB/0004	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)	25/06/2014	19/08/2014	SmPC	

IB/0003/G	This was an application for a group of variations. To update of sections 4.4 and 4.8 of the SmPC to add a warning regarding ophthalmologic complications and to include corneal disorders, keratitis, punctate keratitis and cutaneous lupus erythematosus as adverse drug reactions. The Package Leaflet is updated accordingly. Minor editorial amendments are made to the SmPC and Package Leaflet, following the same changes to Xeloda II-53. To update of section 5.1 of the SmPC with updated efficacy and safety information for XELIRI (CAPIRI) and new efficacy and safety information specifically for XELIRI (CAPIRI) +/- bevacizumab and of sections 4.4 and 4.8 in order to include a warning and information on severe skin reactions as adverse drug reactions, respectively. In addition, section 4.2 of the SmPC is updated in order to include additional dose recommendations on the combination with irinotecan. The Package Leaflet is updated accordingly following the same change to Xeloda II-54. To update of section 4.4 of the SmPC to include acute renal failure as complication of dehydration and of section 4.8 of the SmPC to include acute renal failure secondary to dehydration as an Adverse Drug Reaction (ADR). The Package Leaflet is updated accordingly. In addition, minor changes are made to section 5.1 of the SmPC following the same change	02/05/2014	19/08/2014	SmPC and PL	

	to Xeloda II-55. Update of section 4.4 of the SmPC with regard to prophylactic treatment of hand-foot syndrome. In addition, section 4.5 of the SmPC is updated with regard to interaction with folinic/folic acid upon switching from 5-fluorouracil to capecitabine. The Package Leaflet is updated accordingly following the same change to Xeloda II-57-G. Furthermore, the frequencies of the undesirable side effects listed in the OIL have been aligned to the ones in section 4.8 of the SmPC following the same change to Xeloda N-59. 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				

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IAIN/0002	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	21/11/2013	n/a		
IB/0001	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)	02/09/2013	19/08/2014	SmPC	