EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PhotoBarr

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
T/0027	Transfer of Marketing Authorisation Holder	17/06/2011	27/07/2011	SPC, Labelling, PL	
II/0023	Following the review of the MAH safety database and a literature review, the MAH proposes an update of sections 4.4 of the Summary of Product Characteristics (SmPC) to include information regarding the risk of thrombo-embolic events and hypersensitivity. Recommendation regarding hypersensitivity has also been included in the SmPC. In addition, a revision of section 4.8 of the SmPC is proposed. The Package leaflet (PL) has been updated accordingly. Furthermore, the MAH took the opportunity of this variation to harmonise the SmPC with the Core Data Sheet (CDS) and to revise the product information in line with the latest version of the QRD template (version 7.3). C.I.4 - Variations related to significant modifications of the Summary of Product Characteristics due in particular to new	18/11/2010	06/01/2011	SPC, PL	Following the report of two cases of deep vein thrombosis in relation to PhotoBarr, the MAH conducted a review of all cases of thrombo-embolic events in the company safety database and a literature review. The risk of thrombo-embolic events has been assessed as probably related to PhotoBarr and the MAH has updated sections 4.4 and 4.8 of the SmPC. In addition, following the report of one case of anaphylaxis assessed to be related to photodynamic therapy with PhotoBarr, the MAH has updated sections 4.2, 4.4 and 4.8 to include the risk of hypersensitivity reactions. Furthermore, an analysis of the MAH's post marketing database was conducted by System Organ Class and based on causality assessment, section 4.8 of the SmPC has been updated.

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	quality, pre-clinical, clinical or pharmacovigilance data				
II/0026	to introduce an alternative method for the routine testing of PhotoBarr and to add the corresponding new specification parameter in the finished product specification. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	23/09/2010	01/10/2010		
IA/0025/G	This was an application for a group of variations. To change in the name of manufacturing site Draxis Pharma, a division of Draxis Specialty Pharmaceuticals to DRAXIS Specialty Pharmaceuticals Inc. To change in the adress of a manufacturing site involved in manufacture and testing of Photofrin from Bactimm BV Middenkampweg 17, 6545 CH Nijmegen NL, to Bactimm BV Middenkampweg 19, 6545 CH Nijmegen NL. A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release), A.4 - Administrative change - Change in the name and/or address of a manufacturer/ supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance	04/06/2010	n/a		
IA/0024	A.5.a - Administrative change - Change in the name and/or address of a manufacturer of the manufacturer responsible for batch release	25/05/2010	n/a	Annex II, PL	

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R/0020	Renewal of the marketing authorisation	18/12/2008	04/03/2009	SPC, Annex II, Labelling, PL	
IA/0021	07_a_Replacement/add. of manufacturing site: Secondary packaging site, 08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	12/12/2008	n/a	Annex II, PL	
IA/0019	08_a_Change in BR/QC testing - repl./add. of batch control/testing site	06/09/2007	n/a		
II/0017	Quality changes	19/07/2007	25/07/2007		
IB/0018	14_b_Change in manuf. of active substance without Ph. Eur. certificate - new manufacturer	06/07/2007	n/a		
IB/0016	17_b_Change in the storage conditions for the active substance	18/06/2007	n/a		
IB/0015	30_b_Change in supplier of packaging components - replacement/addition	14/05/2007	n/a		
IB/0013	07_c_Replacement/add. of manufacturing site: All other manufacturing operations ex. batch release, IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	13/04/2007	n/a	Annex II, PL	
II/0012	Update of Summary of Product Characteristics and Package Leaflet	21/09/2006	23/10/2006	SPC, PL	The MAH applied for a type II variation, upon request by the CHMP following the assessment of FUM 024 and FU2 024.1, to update sections 4.2 and 4.4 of the SPC to include further recommendations for patients with hepatic impairment. The PL has been updated accordingly. The influence of hepatic impairment on exposure to PhotoBarr has not been evaluated and no pharmacokinetic and safety data in patients with hepatic impairment are available. Based on evidence for a primarily hepatic/biliary elimination of photoactive substances, severity of phototoxic reactions and duration of the period of photosensitivity in patients with any grade of hepatic impairment may be increased. PhotoBarr is contraindicated in

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					patients with severe hepatic impairment. Patients with mild to moderate hepatic impairment should be clearly instructed that the period requiring precautionary measures due to increased photosensitivity may be longer than 90 days. During this period, patients should wear dark sunglasses, which have an average white light transmittance of <4% when outdoors. The photosensitivity is due to residual photoactive substances, which will be present in all parts of the skin.
II/0010	Quality changes	21/09/2006	25/09/2006		
IA/0011	05_Change in the name and/or address of a manufacturer of the finished product	28/04/2006	n/a		
II/0008	Update of Summary of Product Characteristics, Labelling and Package Leaflet	17/11/2005	23/12/2005	SPC, Annex II, Labelling, PL	The MAH applied for an administrative type II variation to implement minor editorial changes in the Summary of Product Characteristics, Annex II, Labelling and Package Leaflet. In addition, the MAH took the opportunity to bring the annexes line with the latest QRD templates.
II/0007	Update of or change(s) to the pharmaceutical documentation	13/10/2005	18/10/2005		
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/11/2004	n/a	Labelling, PL	
IA/0004	08_a_Change in BR/QC testing - repl./add. of batch control/testing site	29/10/2004	n/a		
IA/0001	08_a_Change in BR/QC testing - repl./add. of batch control/testing site	06/09/2004	n/a		