Foscan

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
PSUSA/2885/ 202404	Periodic Safety Update EU Single assessment - temoporfin	28/11/2024	n/a		PRAC Recommendation - maintenance
PSUSA/2885/ 201904	Periodic Safety Update EU Single assessment - temoporfin	28/11/2019	n/a		PRAC Recommendation - maintenance

[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).

IB/0043/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.5.f - Change to in-process tests or limits applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue B.II.b.5.f - Change to in-process tests or limits	21/02/2018	n/a		

	applied during the manufacture of the finished product - Addition or replacement of an in-process test as a result of a safety or quality issue				
IB/0045	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	12/02/2018	n/a		
IB/0046/G	This was an application for a group of variations. B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	29/01/2018	n/a		
IB/0044/G	This was an application for a group of variations. B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	29/01/2018	n/a		
II/0042	To replace the current manufacturing site Sigma-Aldrich Company Limited, The Old Brickyard, New Road, Gillingham, Dorset, SP8 4XT, United Kingdom, which is currently covered by an ASMF, by the following site Chemcon GmbH, Engesserstr. 4b, 79108 Freiburg im Breisgau, Germany, for the	26/10/2017	n/a		

	manufacture of the active substance temoporfin. The manufacturing process is assessed as part of this procedure. B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier				
IB/0041/G	This was an application for a group of variations. C.I.7.b - Deletion of - a strength C.I.7.b - Deletion of - a strength	29/03/2016	11/11/2016	SmPC, Annex II, Labelling and PL	
IAIN/0040	A.1 - Administrative change - Change in the name and/or address of the MAH	14/01/2016	11/11/2016	SmPC, Labelling and PL	
IAIN/0039	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	09/12/2015	11/11/2016	Annex II and PL	
IAIN/0038	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	11/08/2015	n/a		
II/0036	Submission of a new Risk Management Plan (version 1.0)	23/04/2015	n/a		

	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
PSUV/0037	Periodic Safety Update	04/12/2014	n/a		PRAC Recommendation - maintenance
IAIN/0035/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	24/07/2014	08/07/2015	Annex II and PL	
IAIN/0034/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	05/06/2014	08/07/2015	SmPC, Labelling and PL	
N/0033	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/05/2013	11/10/2013	Labelling and	

				PL	
II/0030/G	This was an application for a group of variations. - To add new manufacturer of the active substance that is supported by an ASMF - To increase the limit of an known impurity to increase the specification level for the unknown impurity of the active substance. B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is supported by an ASMF B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	13/12/2012	n/a		
IA/0032	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	13/11/2012	n/a		
IB/0031	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)	21/09/2012	29/10/2012	SmPC	
R/0027	Renewal of the marketing authorisation.	21/07/2011	22/09/2011	SmPC, Annex II, Labelling and PL	Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit risk balance, the CHMP is of the opinion that the quality, safety and efficacy of this medicinal product continues to be

					adequately and sufficiently demonstrated and therefore considered that the benefit risk profile of Foscan continues to be favourable. The CHMP recommends the renewal of the Marketing Authorisation with unlimited validity.
IB/0029	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)	09/09/2011	n/a	SmPC	
IA/0028/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS 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.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	04/07/2011	n/a		
IB/0025	IB_42_a_01_Change in shelf-life of finished product - as packaged for sale	16/04/2009	n/a	SmPC, Labelling and PL	
IA/0024	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	23/01/2009	n/a		

S/0023	Annual re-assessment.	19/03/2008	21/05/2008	SmPC, Annex II, Labelling and PL	As part of the initial MA, the MAH had agreed to comply with the following two remaining Specific Obligations: - To conduct a confirmatory study (TEM-HNC-001) of the palliative benefits of temoporfin in patients with advanced disease; - and to maintain a patient registry until the results of this confirmatory study have been submitted and reviewed by the CHMP. Study TEM-HNC-001 was a confirmatory multicentre, multinational, single-group, open-label, single-dose study. The primary objective was to assess overall tumour response in patients with advanced squamous cell carcinoma of the head and neck who have failed prior therapies and are unsuitable for curative therapy with radiotherapy, surgery or systemic therapy. The secondary objectives of the study were to assess complete tumour response; duration of tumour response; time to disease progression, quality of life, survival, Eastern Cooperative Oncology Group (ECOG) performance status and weight, patient global assessment of treatment benefit, and the toxicity, tolerability and safety of Foscan-photodynamic therapy (PDT). A total of 43 patients were enrolled in the study, 39 patients were treated and analysed of which 19 achieved a complete response (CR) and 2 patients a partial response (PR), resulting in an overall response rate of 54% (95% CI: 37%; 70%). Median progression free survival (PFS) for responding patients was 131 weeks while PFS was 31 weeks for all patients studied. The estimated 40-week survival rate for responders was 91%, while this was 39%

					for the non-responders and 67% for the entire population studied. Furthermore, during the study, 20 patients (51%) maintained the same performance status, 15 patients (39%) had an improvement from ECOG 1 to 0 and 3 patients (8%) experienced deterioration from ECOG 0 to 1. Response rates were observed to be higher and durations of response and survival were considerably longer in the present study than in the earlier performed study 009.003.08b (provide
II/0022	Quality changes	18/10/2007	23/10/2007		
X/0019	Annex I_2.(c) Change or addition of a new strength/potency	19/07/2007	15/10/2007	SmPC, Labelling and PL	
IA/0021	IA_08_a_Change in BR/QC testing - repl./add. of batch control/testing site	25/04/2007	n/a		
S/0020	5th annual re-assessment	22/02/2007	13/04/2007	Annex II	Based on the provided information, the Benefit/Risk assessment of Foscan remains unchanged. The Marketing Authorisation should be maintained under exceptional circumstances until the pending Specific Obligations are fulfilled. No relevant new safety data became available during the period under review. Based on the data provided, there is no need to update the SPC, labelling and Package Leaflet. The CHMP considered that there is no longer any need for the Marketing Authorisation Holder to provide yearly PSURs. The Committee considered that subsequent PSURs could be submitted every 3 years.

R/0018	Renewal of the marketing authorisation.	21/09/2006	29/11/2006	SmPC, Annex II, Labelling and PL	Based upon the data that have become available since the granting of the initial Marketing Authorisation, the CHMP considers that the benefit-risk balance of Foscan remains positive, but considers that its safety profile is to be closely monitored for the following reasons: Due to the limited patient exposure so far and the safety profile of Foscan which includes some serious side effects such as photosensitivity, all adverse reactions that will be reported, will need to be carefully considered. Therefore, the CHMP decided that the MAH should continue to submit yearly PSURs. Furthermore, Foscan remains under exceptional circumstances due to two unresolved specific obligations, which will generate further efficacy and safety data in the future. The benefit-risk balance of the product will continue to be reviewed annually as part of the Annual Re-assessments. Therefore, based upon the safety profile of Foscan, which requires the submission of yearly PSURs, the CHMP concluded that the MAH should submit one additional renewal application in 5 years time. As part of the renewal procedure, the following statement was added to section 4.4 of the SPC and the PL has been updated accordingly: "For 6 months following Foscan treatment avoid prolonged direct sunlight exposure of the injection site arm. As a precautionary measure, if prolonged outdoor activity is planned, the injection arm should be protected by wearing a long sleeved, coloured shirt."

					Changes were also made to the product information to bring it in line with the current EMEA/QRD template, SPC guideline and other relevant guideline(s), which were reviewed by QRD and accepted by the CHMP.
S/0017	Annual re-assessment.	28/06/2006	28/06/2006		The CHMP, having reviewed the evidence of compliance with the Specific Obligations submitted and having re-assessed the benefit/risk profile of the medicinal product, recommended that the Marketing Authorisation should remain under exceptional circumstances. The benefit/risk balance of Foscan remains unchanged. The MA should be maintained under exceptional circumstances until the pending specific obligations are fulfilled.
IA/0016	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	23/09/2005	n/a		
IA/0015	IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	01/09/2005	n/a	Annex II and PL	
IA/0014	IA_01_Change in the name and/or address of the marketing authorisation holder	17/08/2005	n/a	SmPC, Labelling and PL	
S/0012	Annual re-assessment.	20/01/2005	29/03/2005	Annex II	The CHMP, having reviewed the evidence of compliance with the Specific Obligations submitted and having re-assessed the benefit/risk profile of the medicinal product, recommended that the Marketing Authorisation should remain under exceptional circumstances. The MAH shall complete the following programme of studies within specified time frames, the results of which shall form

					the basis of the annual reassessments of the benefit/risk profile: - The MAH commits to conduct a study confirming the palliative benefits of Foscan PhotoDynamic Therapy (PDT) in patients with advanced disease; - The MAH commits to maintaining a register of patients treated with Foscan, until the results of the above-mentioned confirmatory study are available and have been reviewed by the CHMP.
IB/0013	IB_42_a_01_Change in shelf-life of finished product - as packaged for sale	11/03/2005	n/a	SmPC	
T/0011	Transfer of Marketing Authorisation	18/11/2004	05/01/2005	SmPC, Labelling and PL	
S/0010	Annual re-assessment.	20/11/2003	20/02/2004	Annex II	
I/0009	20_Extension of shelf-life as foreseen at time of authorisation	09/09/2003	20/10/2003	SmPC	
I/0008	20a_Extension of shelf-life or retest period of the active substance	15/08/2003	20/08/2003		
S/0007	Annual re-assessment.	19/03/2003	09/07/2003	Annex II	
I/0005	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	11/11/2002	09/12/2002	Annex II and PL	
I/0006	11a_Change in the name of a manufacturer of the active substance	06/11/2002	12/11/2002		

T/0004	Transfer of Marketing Authorisation	06/08/2002	13/09/2002	SmPC, Labelling and PL	
I/0002	01_Change following modification(s) of the manufacturing authorisation(s)	25/01/2002	12/04/2002	Annex II and PL	
I/0003	11a_Change in the name of a manufacturer of the active substance	17/01/2002	06/03/2002		
T/0001	Transfer of Marketing Authorisation	11/12/2001	19/02/2002	SmPC, Labelling and PL	