Myocet liposomal

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
T/0073	Transfer of Marketing Authorisation	22/04/2024	29/05/2024	SmPC, Labelling and PL	
PSUSA/1172/ 202211	Periodic Safety Update EU Single assessment - doxorubicin	22/06/2023	22/06/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

[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).

					PSUSA/1172/202211.
II/0070	Update of section 4.6 of the SmPC, upon request by PRAC following the assessment of EMEA/H/C/PSUSA/00001172/202111, to align the wording with the published CHMP SWP advice on the duration of contraception in female patients after cessation of treatment with genotoxic drug. The Package Leaflet has been updated accordingly. C.I.3.b - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Change(s) with new additional data submitted by the MAH	15/12/2022	25/01/2024	SmPC and PL	SmPC new text Update of section 4.6 of the SmPC with a recommended duration of the contraception period for women of child-bearing potential following end of treatment of 6.5 months and to include a recommendation to seek advice for genetic counselling and fertility preservation. The Package Leaflet (PL) is updated accordingly.
IG/1561	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	18/11/2022	n/a		
IB/0069/G	This was an application for a group of variations. B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	22/09/2022	n/a		
IB/0068/G	This was an application for a group of variations.	22/07/2022	n/a		

	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
PSUSA/1172/ 202111	Periodic Safety Update EU Single assessment - doxorubicin	07/07/2022	n/a		PRAC Recommendation - maintenance
II/0066	B.II.a.3.b.2 - Changes in the composition (excipients) of the finished product - Other excipients - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the product	25/11/2021	n/a		
IA/0065	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	19/03/2021	n/a		
IA/0064	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	18/09/2020	n/a		
IB/0063	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	26/08/2020	19/10/2020	SmPC, Annex II, Labelling and PL	
IA/0062/G	This was an application for a group of variations.	10/07/2020	n/a		

	B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer				
IA/0061	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	13/05/2020	n/a		
IAIN/0060	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	24/10/2019	19/10/2020	SmPC, Labelling and PL	
PSUSA/1172/ 201811	Periodic Safety Update EU Single assessment - doxorubicin	25/07/2019	25/07/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/1172/201811.
IB/0058	B.II.z - Quality change - Finished product - Other variation	23/10/2018	n/a		
IA/0057/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	20/07/2018	18/07/2019	Annex II and PL	

PSUSA/1172/201511	Periodic Safety Update EU Single assessment - doxorubicin	07/07/2016	n/a		PRAC Recommendation - maintenance
IAIN/0056	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	14/06/2016	n/a		
T/0054	Transfer of Marketing Authorisation	08/01/2015	27/01/2015	SmPC, Labelling and PL	
IA/0053	A.7 - Administrative change - Deletion of manufacturing sites	20/11/2014	n/a		
IB/0051	B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products	20/08/2014	n/a		
IA/0052	A.7 - Administrative change - Deletion of manufacturing sites	11/08/2014	n/a		
IAIN/0050	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/05/2014	27/01/2015	SmPC, Annex II, Labelling and PL	
IB/0048	B.II.z - Quality change - Finished product - Other variation	06/05/2014	n/a		
IA/0049	A.7 - Administrative change - Deletion of manufacturing sites	29/04/2014	n/a		
PSUV/0046	Periodic Safety Update	27/06/2013	02/10/2013		Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

					PSUV/0046.
IAIN/0047	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	15/07/2013	n/a		
IA/0045	B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer	08/02/2013	n/a		
T/0044	MA Transfer from Cephalon Europe to Teva Pharma B.V. Transfer of Marketing Authorisation	12/12/2012	14/01/2013	SmPC, Labelling and PL	
IB/0043/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	26/07/2012	n/a		
IB/0042	A.2.z - Change in the (invented) name of the medicinal product - Other changes	21/05/2012	29/10/2012	SmPC, Annex II, Labelling and PL	
IAIN/0041	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	30/03/2012	29/10/2012	Annex II and PL	
IA/0040	B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur.	17/02/2012	n/a		

	Monograph - Updated certificate from an already approved manufacturer				
IB/0039/G	This was an application for a group of variations. B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.g - Change in the specification parameters and/or limits of the finished product - Addition or replacement (excluding biological or immunological product) of a specification parameter as a result of a safety or quality issue	16/12/2011	n/a		
N/0038	The MAH applied to correct some errors in section 4 of Patient Leaflet to align with section 4.8 of SmPC. Additionally, linguistic amendments were introduced in some languages following the linguistic review Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/08/2011	n/a	PL	
IB/0037	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	14/07/2011	21/07/2011	SmPC, Labelling and PL	

IB/0036	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	22/06/2011	n/a		
IA/0035	B.III.1.a.3 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)	08/06/2011	n/a		
II/0031/G	This was an application for a group of variations. Update of section 4.4 of the Summary of Product Characteristics (SmPC) to include radiation recall based on post marketing and clinical data reviewed by the MAH. Section 4.4 of the SmPC has also been updated to amend the wording regarding cardiac toxicity, myelosuppression and gastrointestinal disorders as requested by the CHMP during the evaluation of the renewal procedure. In addition, the Package Leaflet has been updated to reflect the above changes and the user testing results. In addition, further to the results of the user testing, the name of an excipient is changed in the PL and Labelling and accordingly in the SmPC. C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46,	17/02/2011	24/03/2011	SmPC, Labelling and PL	

	or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH				
IA/0034	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)	25/01/2011	n/a		
IB/0033	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)	09/12/2010	n/a		
IB/0032/G	This was an application for a group of variations. 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 batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling	17/08/2010	n/a		

	down to 10-fold B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
R/0030	Renewal of the marketing authorisation.	22/04/2010	02/07/2010	SmPC, Annex II, Labelling and PL	Based on the review of the available information the CHMP is of the opinion that the quality, the safety and the efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and considers that the benefit/risk profile of Myocet continues to be favourable. The CHMP therefore recommended that a renewal can be granted with unlimited validity. With this procedure the MAH also updated the product information (PI). This update was made so that the PI would be in line with the current QRD requirements and the SmPC guideline.
II/0027	Addition of a test to the Drug Product release specification and update of several analytical methods to be in line with Ph. Eur. methods. Opportunity is taken to submit additional supportive stability data. Quality changes	17/12/2009	06/01/2010		
IA/0029	IA_15_a_Submission of Ph. Eur. certificate for active substance - approved manufacturer	29/11/2009	n/a		
IA/0028	IA_09_Deletion of manufacturing site	15/10/2009	n/a	Annex II and PL	

II/0026	The MAH has applied to update section 4.4 of the SPC to warn practitioners to monitor the cardiac function of patients concomitantly treated with trastuzumab, as well as to update section 4.8 of the SPC to add "cardiomyopathy" as undesirable effect following the 10th PSUR assessment. MAH has also taken an opportunity to implement editorial changes to SPC, Annex II, Labelling and Package Leaflet. Update of Summary of Product Characteristics, Labelling and Package Leaflet	23/10/2008	24/11/2008	SmPC, Annex II, Labelling and PL	SPC section 4.4 was updated with the information that patients concomitantly treated with Myocet and trastuzumab must be appropriately monitored for the cardiac function due to the known increased risk of cardiotoxicity of anthracyclines when combined with trastuzumab. Furthermore, in order to clarify what types of ECG changes are more indicative of cardiac toxicity the relevant paragraph was amended with information on reduction of QRS complex. In addition, the term "cardiomyopathy" was added as undesirable effect in the section of Cardiac Disorders in SPC section 4.8.
II/0025	Update of or change(s) to the pharmaceutical documentation	25/09/2008	27/10/2008	Annex II and PL	
IA/0024	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	06/06/2008	n/a		
IA/0023	IA_22_a_Submission of TSE Ph. Eur. certificate for exc. - Approved/new manufacturer	01/02/2008	n/a		
IA/0022	IA_22_a_Submission of TSE Ph. Eur. certificate for exc. - Approved/new manufacturer	03/10/2007	n/a		
T/0021	Transfer of Marketing Authorisation	07/05/2007	04/06/2007	SmPC, Labelling and PL	Transfer of the Marketing Authorisation from Zeneus Pharma Limited to Cephalon Europe.
IA/0019	IA_22_a_Submission of TSE Ph. Eur. certificate for exc. - Approved/new manufacturer	22/02/2007	n/a		
T/0018	Transfer of Marketing Authorisation	29/06/2006	28/07/2006	SmPC,	Transfer of the Marketing Authorisation from Elan Pharma

				Labelling and PL	International Ltd to Zeneus Pharma Limited.
IB/0017	IB_07_c_Replacement/add. of manufacturing site: All other manufacturing operations ex. batch release	18/04/2006	n/a		
R/0014	Renewal of the marketing authorisation.	23/06/2005	15/09/2005	SmPC, Annex II, Labelling and PL	
IA/0016	IA_22_a_Submission of TSE Ph. Eur. certificate for exc. - Approved/new manufacturer	25/04/2005	n/a		
IA/0015	IA_09_Deletion of manufacturing site	25/04/2005	n/a		
I/0013	01_Change in the name of a manufacturer of the medicinal product	23/04/2003	02/05/2003		
I/0009	25_Change in test procedures of the medicinal product	12/02/2003	26/02/2003		
I/0012	25_Change in test procedures of the medicinal product	14/01/2003	21/01/2003		
I/0011	25_Change in test procedures of the medicinal product	14/01/2003	21/01/2003		
I/0010	25_Change in test procedures of the medicinal product	08/01/2003	13/01/2003		
I/0008	25_Change in test procedures of the medicinal product	08/01/2003	13/01/2003		

I/0007	01_Change following modification(s) of the manufacturing authorisation(s)	25/11/2002	18/12/2002	Annex II and PL	
I/0006	22_Change in shelf-life after reconstitution	28/02/2002	12/04/2002	SmPC, Labelling and PL	
II/0005	Quality changes	20/09/2001	21/03/2002	SmPC and PL	
I/0004	19_Change in specification of excipients in the medicinal product (excluding adjuvants for vaccines)	19/09/2001	23/10/2001		
T/0001	Transfer of Marketing Authorisation	24/01/2001	21/03/2001	SmPC, Labelling and PL	
II/0002	Update of Summary of Product Characteristics and Package Leaflet	16/11/2000	20/03/2001	SmPC and PL	