EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MabCampath

Procedural steps taken and scientific information after the authorisation

Changes made after 1 December 2004

For procedures finalised before 1 December 2004, please refer to 'Procedural steps taken until cut-off date'

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
N/0055	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/06/2012	n/a	PL	
R/0054	Renewal of the marketing authorisation.	17/03/2011	12/05/2011	SPC, Annex II, 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 MabCampath continues to be favourable. The CHMP is also of the opinion that the renewal can be granted with unlimited validity. The PSUR cycle for this product should be maintained as a once-yearly submission as currently a number of adverse events are under close surveillance.
II/0053	The change relates to the replacement of	22/04/2010	05/05/2010		

[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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No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
	raw material and suppliers used in the cell culture process in the manufacturing process of the active substance. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological active substance or a starting material […] used in the manufacture of a biological/immunological product				
II/0052	Increase to the current fill volume of MabCampath. The currently approved fill volume of 1.1 ml will be increased to 1.15ml. Change(s) to the manufacturing process for the finished product	21/01/2010	04/02/2010		
N/0050	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/11/2009	n/a	PL	
II/0049	Addition of a manufacturing site for the finished product Quality changes	22/10/2009	26/11/2009		
II/0047	Changes to the manufacturing process for the active substance. Change(s) to the manufacturing process for the active substance	19/11/2009	26/11/2009		
II/0048	Addition of a manufacturer of the active substance Quality changes	22/10/2009	20/11/2009	Annex II	

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IA/0051	16_b_Submission of new TSE certificate relating to active substance - other substances	20/11/2009	n/a		
N/0043	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/07/2009	n/a	PL	
IA/0046	25_b_01_Change to comply with Ph. - compliance with EU Ph. update - active substance	13/07/2009	n/a		
IA/0045	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	25/06/2009	n/a	Annex II, PL	
IA/0044	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	25/06/2009	n/a	Annex II, PL	
N/0042	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	11/05/2009	n/a	PL	
II/0040	Update of SPC section 4.4 regarding the wording on transfusion associated graft versus host disease (TAGVHD). In addition, SPC sections 4.2, 4.3, 4.4, 4.8 and 4.9 are proposed to be updated and corrected based on the latest version of the CCDS. Section 2 of the PL is proposed to be amended accordingly. Update of Summary of Product Characteristics, Labelling and Package Leaflet	23/10/2008	05/12/2008	SPC, Annex II, PL	A fatal case of Transfusion Associated Graft Versus Host Disease (TAGVHD) was reported in an investigator sponsored study CALGB 10101. TAGVHD is a rare and generally fatal immunological complication of transfusion practice, involving the engraftment and clonal expansion of viable donor lymphocytes contained in transfused blood components in a susceptible host. Although the induction and consolidation treatment regimen received by this patient may have facilitated the development of TAGVHD, no individual agent can be identified as the sole or pre-eminent cause, since each drug has complex immunosuppressive properties, potentially increasing the susceptibility to developing TAGVHD. B-CLL patients may also be at increased risk of TAGVHD. Therefore, SPC section 4.4 has been updated to recommend that patients who have been treated with alemtuzumab receive irradiated blood products. In addition, various updates and corrections to SPC sections 4.2,

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					4.3, 4.4, 4.8 and 4.9 as well as PL section 2 have been performed based on the latest version of the Company Core Data Sheet. In particular, in section 4.2 the information on dose adjustments considering haematologic values has been further clarified regarding the recommended dose for patients who initiate therapy with a low absolute neutrophil count or platelate count and those patients who develop neutropenia and thrombocytopenia during treatment. SPC section 4.8 has been revised in order to make clear which undesirable effects were observed during post-marketing as well as to improve readability and avoid redundancies. Furthermore, Annex 2 has been updated with reference to the latest approved Risk Management Plan version.
II/0037	Change in test procedures for active substance and finished product. Change(s) to the test method(s) and/or specifications for the active substance	24/07/2008	29/07/2008		
S/0035	6th annual re-assessment Annual reassessment	24/04/2008	04/07/2008	SPC, Annex II, Labelling, PL	The CHMP, having reviewed the evidence of compliance with the specific obligations submitted by the Marketing Authorisation Holder and having reassessed the benefit/risk profile of MabCampath concluded that the benefit/risk remains favourable and since all specific obligations have been fulfilled, there are no remaining grounds for the Marketing Authorisations to remain under exceptional circumstances. The SPC, Annex II, labelling and the Package Leaflet have been updated in line with the conclusions of the CHMP to reflect the fact that the Marketing Authorisation is no longer under exceptional circumstances.
IB/0039	15_b_01_Submission of Ph. Eur. certificate for active substance - new manuf./sterile substance	04/07/2008	n/a		
IA/0038	15_a_Submission of Ph. Eur. certificate for active substance - approved manufacturer	06/06/2008	n/a		
N/0036	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/03/2008	n/a	PL	

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N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	14/02/2008	n/a	PL	
II/0030	Extension of the indication in the treatment of B-cell chronic lymphocytic leukaemia (B-CLL) in patients for whom fludarabine combination chemotherapy is not appropriate. Extension of Indication	18/10/2007	19/12/2007	SPC, Annex II, PL	Please refer to Scientific Discussion: MabCampath-H-353-II-30.
II/0028	Change(s) to the manufacturing process for the finished product	19/07/2007	23/07/2007		
IA/0033	05_Change in the name and/or address of a manufacturer of the finished product	20/04/2007	n/a	Annex II, PL	
IB/0032	38_b_Change in test procedure of finished product - minor change, biol. active subst./excipient	08/05/2007	n/a	IB/0032	
IB/0031	38_b_Change in test procedure of finished product - minor change, biol. active subst./excipient	08/05/2007	n/a		
S/0027	5th Annual Reassessment Annual reassessment	22/03/2007	22/03/2007		The CHMP, having reviewed the evidence of compliance with the specific obligations submitted by the Marketing Authorisation Holder and having re-assessed the benefit/risk profile of the medicinal product, recommended that no amendment of the Annexes of the Commission Decision is necessary and that the marketing authorisation remains under exceptional circumstances.
II/0026	Change(s) to the manufacturing process for the active substance	22/02/2007	28/02/2007		
R/0022	Renewal of the marketing authorisation	01/06/2006	28/07/2006	SPC, Annex II, Labelling, PL	
II/0021	Change(s) to the test method(s) and/or specifications for the active substance	23/03/2006	29/03/2006		
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3	08/11/2005	n/a	PL	

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	Notification)				
S/0019	Annual reassessment	13/10/2005	13/10/2005		On the basis of the submitted data, the CHMP, having reviewed the compliance with the specific obligations submitted by the MAH and having re-assessed the benefit/risk profile of the medicinal product, is of the opinion that the quality, safety and efficacy continues to be to be favourable for MabCampath in the approved indication. It is recommended that the marketing authorisation remains under exceptional circumstances.
T/0018	Transfer of Marketing Authorisation Holder	15/07/2005	16/08/2005	SPC, Labelling, PL	The Marketing Authorisation Holder was transferred from ILEX Pharmaceuticals Ltd to Genzyme Europe BV.
II/0017	Change(s) to container	21/04/2005	27/04/2005		
IB/0016	42_a_01_Change in shelf-life of finished product - as packaged for sale	16/02/2005	n/a	SPC	