EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Refludan

Procedural steps taken and scientific information after the authorisation

Changes made after 1 August 2003

For procedures finalised before 1 August 2003, please refer to 'Procedural steps taken until cut-off date'

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amendment	Product Information affected[3]	Summary
IA/0041	A.1 - Administrative change - Change in the name and/or address of the MAH	02/09/2011	n/a	SPC, Labelling, PL	
II/0040	Removal of an identity test from the drug substance specifications. Current marketing authorisation includes other tests which prove the batch to batch amino acid composition and integrity of the Lepirudin molecule. This is according to current guideline (ICH Q6B) Change(s) to the test method(s) and/or specifications for the active substance	19/02/2009	26/02/2009		
II/0039	The MAH has applied to widden the finish product shelf-life specifications. The	18/12/2008	05/01/2009		

[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 A 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).

7 Westferry Circus ● Canary Wharf ● London, E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0) 20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
	specifications at release remain unchanged. Change(s) to the test method(s) and/or specifications for the finished product				
T/0038	Transfer of Marketing Authorisation	03/10/2008	04/11/2008	SPC, Labelling, PL	Transfer from Pharmion Ltd. to Celgene Europe Ltd.
II/0037	Changes to approved test methods to the finished product Change(s) to the test method(s) and/or specifications for the finished product	25/09/2008	01/10/2008		
N/0036	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/07/2008	n/a	PL	
II/0035	Minor changes to test procedures for the active substance and finished product. In addition, to update excipient specifications in accordance with Ph. Eur. Change(s) to the test method(s) and/or specifications for the finished product	30/05/2008	05/06/2008		
II/0033	Quality changes	24/04/2008	28/04/2008		
N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/03/2008	n/a	PL	
II/0032	Change(s) to the manufacturing process for the active substance	24/01/2008	29/01/2008		
IA/0031	04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.), 05_Change in the name and/or address of a manufacturer of the finished product	15/10/2007	n/a	Annex II, PL	
II/0029	Change to the test procedure and/or specification of a raw material	26/04/2007	03/05/2007		
R/0026		14/12/2006	05/03/2007	SPC, Annex II,	Refludan continues to show a significant benefit in adult patients

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
	Refludan continues to show a significant benefit in adult patients with heparin-induced thrombocytopenia (HIT) type II and thromboembolic disease mandating parental antiththrombic therapy. No new safety-related signals or changes in the frequency of listed ADRs have been identified from the data presented. The benefit/risk remains positive.			Labelling, PL	with heparin-induced thrombocytopenia (HIT) type II and thromboembolic disease mandating parental antiththrombic therapy. No new safety-related signals or changes in the frequency of listed ADRs have been identified from the data presented. The benefit/risk remains positive.
II/0028	Quality changes	24/01/2007	31/01/2007		
IA/0027	04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.)	27/11/2006	n/a		
II/0024	Change(s) to the test method(s) and/or specifications for the finished product	27/04/2006	03/05/2006		
II/0021	Quality changes	17/11/2005	23/11/2005		
IA/0022	01_Change in the name and/or address of the marketing authorisation holder	05/08/2005	n/a	SPC, Labelling, PL	
IA/0020	04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.)	07/06/2005	n/a	Annex II, PL	
IB/0019	42_a_01_Change in shelf-life of finished product - as packaged for sale	04/04/2005	n/a	SPC	
T/0018	Transfer of Marketing Authorisation	14/07/2004	02/09/2004	SPC, Labelling, PL	Transfer of MAH from Schering AG to Pharmion Ltd.
II/0016	Update of Summary of Product Characteristics and Package Leaflet	25/04/2003	14/07/2003	SPC, PL	
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/04/2003	12/05/2003	PL	
R/0014	Renewal of the marketing authorisation	17/01/2002	25/04/2002	SPC, Annex II, Labelling, PL	
T/0015	Transfer of Marketing Authorisation	21/12/2001	19/02/2002	SPC, Labelling, PL	

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
II/0012	Update of Summary of Product Characteristics and Package Leaflet	18/10/2001	06/02/2002	SPC, Labelling, PL	
I/0013	03_Change in the name and/or address of the marketing authorisation holder	03/10/2001	20/11/2001	SPC, Labelling, PL	
I/0011	01_Change following modification(s) of the manufacturing authorisation(s)	31/08/2001	19/10/2001	Annex II, PL	
II/0010	Update of or change(s) to the pharmaceutical documentation	26/04/2001	11/05/2001		
II/0008	Quality changes	16/09/1998	16/03/1999	SPC, Labelling, PL	
I/0007	15_Minor changes in manufacture of the medicinal product	24/09/1997	n/a		
I/0005	01_Change following modification(s) of the manufacturing authorisation(s)	06/06/1997	27/08/1997	Annex II	
T/0003	Transfer of Marketing Authorisation	06/06/1997	01/07/1997	SPC, Labelling, PL	
I/0004	11_Change in or addition of manufacturer(s) of active substance	18/06/1997	n/a		
I/0002	12_Minor change of manufacturing process of the active substance	18/06/1997	n/a		
I/0001	12_Minor change of manufacturing process of the active substance	18/06/1997	n/a		
I/0006	01_Change following modification(s) of the manufacturing authorisation(s)	17/06/1997	n/a		