EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Revasc

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
IAIN/0033/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.h - Changes to an existing pharmacovigilance	19/10/2012	n/a		

[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).

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	system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system				
IAIN/0032/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	03/05/2012	n/a		
IAIN/0031/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	23/01/2012	n/a	SmPC, Labelling and PL	
II/0030	C.I.8.a - Introduction of a new Pharmacovigilance system - which has not been assessed by the relevant NCA/EMA for another product of the same MAH	17/03/2011	20/04/2011	Annex II	

II/0028	Change to the manufacturer of the active substance with consequential changes to the manufacturing process of the active substance. Change(s) to the manufacturing process for the active substance Change(s) to the test method(s) and/or specifications for the active substance Quality changes	19/11/2009	21/12/2009	Annex II	
II/0029	Changes to the test methods for the active substance and for the finished product Change(s) to the test method(s) and/or specifications for the active substance Change(s) to the test method(s) and/or specifications for the finished product	19/11/2009	25/11/2009		
IB/0027	IB_36_a_Change in shape or dimensions of the container/closure - sterile ph. forms/biologicals	23/03/2009	n/a		
IA/0026	IA_05_Change in the name and/or address of a manufacturer of the finished product	20/09/2007	n/a	Annex II and PL	
R/0025	Renewal of the marketing authorisation.	26/04/2007	21/06/2007		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 Revasc continues to be favourable.

					The CHMP is also of the opinion that the renewal can be granted with unlimited validity.
II/0021	Quality changes	22/02/2007	27/02/2007		
IA/0024	IA_08_b_01_Change in BR/QC testing - repl./add. manuf. responsible for BR - not incl. BC/testing	29/11/2006	n/a	PL	
IA/0022	IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	23/11/2006	n/a		
IA/0023	IA_05_Change in the name and/or address of a manufacturer of the finished product	23/11/2006	n/a		
II/0020	Change(s) to the test method(s) and/or specifications for the finished product	26/01/2006	02/02/2006		
IB/0019	IB_42_a_01_Change in shelf-life of finished product - as packaged for sale	21/12/2005	n/a	SmPC	
IB/0018	The MAH applies for a new pack size for Revasc. The additional pack size proposed in this variation is one vial of Revasc (15 mg) and one ampoule of mannitol (0.5 ml). IB_41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	31/05/2005	31/05/2005	SmPC, Labelling and PL	
IA/0017	Replacement of the manufacturing site responsible of secondary packaging to a new site. IA_07_a_Replacement/add. of manufacturing site: Secondary packaging site	27/05/2005	n/a		

T/0016	Transfer of Marketing Authorisation	25/08/2004	13/10/2004	SmPC, Annex II, Labelling and PL	Transfer from Aventis Pharma S.A. to Canyon Pharmaceuticals.
II/0012	Update of Summary of Product Characteristics and Package Leaflet	25/09/2003	27/01/2004	SmPC, Labelling and PL	
I/0014	24_Change in test procedure of active substance	26/06/2003	01/07/2003		
I/0015	25_Change in test procedures of the medicinal product	26/06/2003	01/07/2003		
R/0011	Renewal of the marketing authorisation.	30/05/2002	02/08/2002		
II/0010	Update of Summary of Product Characteristics and Package Leaflet	19/10/2000	22/01/2001	SmPC, Labelling and PL	
II/0008	Change(s) to the test method(s) and/or specifications for the finished product	26/07/2000	02/08/2000		
I/0009	03_Change in the name and/or address of the marketing authorisation holder	16/06/2000	01/08/2000	SmPC, Labelling and PL	
I/0006	24_Change in test procedure of active substance	15/03/2000	n/a		
I/0007	25_Change in test procedures of the medicinal product	15/03/2000	n/a		
I/0005	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	28/07/1999	29/07/1999		

I/0004	20_Extension of shelf-life as foreseen at time of authorisation	17/12/1998	12/03/1999	SmPC	
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/12/1998	26/01/1999	PL	
I/0001	01_Change following modification(s) of the manufacturing authorisation(s)	11/06/1998	18/09/1998	Annex II, Labelling and PL	
T/0002	Transfer of Marketing Authorisation	11/06/1998	05/08/1998	SmPC, Labelling and PL	