STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 May 2002 please refer to module 8B.

Extension (change of source of active substance)

The company Hoechst Marion Roussel GmbH, Germany, submitted on 1 October 1997 to the EMEA an application to obtain a Marketing Authorisation in accordance with Annex II of Commission Regulation (EC) No 542/95 of 10 March 1995 (part VI) for the medicinal product Insuman (human insulin).

- The procedure for Insuman started on 24 October 1997.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 9 January 1998.
- During the CPMP plenary meeting on 24 February 1998, the CPMP adopted the consolidated list of questions for Insuman to be sent to the company. The CPMP consolidated list of questions was sent to the company on 25 February 1998.
- The company submitted the responses to the consolidated list of questions on 8 April 1998.
- The Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 25 May 1998.
- The CPMP, during its meeting on 23 June 1998, discussed the recommendations presented by the Rapporteur, considering the responses provided by the company satisfactory.
- The CPMP during its meeting of 23-25 June 1998 issued a positive opinion for granting a Marketing Authorisation to Insuman on 24 June 1998.
- The Commission Decision for this extension was issued on 11 November 1998.

Subsequent extensions

Additional route of administration for Insuman Rapid: intravenous use

On 20 January 2000, the CPMP issued a positive opinion for Insuman Rapid, intravenous use. Insuman Rapid administered intravenously is suitable for the treatment of hyperglycaemic coma and ketoacidosis, as well as for achieving pre-, intra- and post-operative stabilisation in patients with diabetes mellitus. In addition the Part II of the dossier was updated to take into account the change in Insuman Rapid from the previous source (insulin HGT) to the new source of active ingredient (insulin HR1799). Minor changes to the manufacturing process were also introduced. The Commission Decision for this extension was issued on 01 August 2000.

Variations

All variations and notifications agreed upon after granting the Marketing Authorisation are summarised in the table below.

Scope	Type of modification[1]	Submission date	Notification/ Opinion Date	CPMP opinion	Change in Comm. Decision	Date of Comm. Decision	
Additional pack size: 4 cartridges for Insuman (Rapid, Basal, Comb 15, Comb 25, Comb 50)	II	27.11.98	16.12.99	Change accepted	Annex I, III	18.02.99	1
Additional pack size: 10 cartridges for Insuman (Rapid, Basal, Comb 15, Comb 25, Comb 50)	II	27.11.98	16.12.99	Change accepted	Annex I, III	18.02.99	2
Additional presentations: Insuman in a pre-filled disposable injection pen: Insuman OptiSet (Rapid, Basal, Comb 15, Comb 25, Com 50)	II	12.07.99	18.11.99	Change accepted	Annex I, III	20.03.00	4
Update of Part II of the dossier to take into account the change from the previous source (insulin HGT) to the new source of active ingredient (insulin HR1799) and additional minor changes to the manufacturing process	II	10.08.99	20.01.00	Change accepted	-	22.02.00	5
Change to the specifications of the active substance	II	13.10.99	13.04.00	Change accepted	-	28.04.00	6
Change in test procedure of active substance	I/II	05.07.00	19.10.00	Change accepted	-	15.11.00	7
Change(s) to the manufacturing process for the active substance	II	05.08.00	19.10.00	Change accepted	-	15.11.00	8
Update of Summary of Product Characteristics and Package Leaflet	II	16.08.00	14.12.00	Change accepted	I, IIIA, IIIB	14.06.01	9
Change in the name and/or address of the marketing authorisation holder (from Hoechst Marion Roussel Deutschland GmbH to Aventis Pharma Deutschland GmbH) Change following modification(s) of the manufacturing authorisation(s) Change in the name of a manufacturer of the active substance	I	14.08.00	21.12.00	Change accepted	I, II, IIIA, IIIB	-	10
Update of or change(s) to the pharmaceutical documentation	II	01.12.00	26.04.01	Change accepted	-	04.05.01	11
Change in specification of medicinal product	I	08.10.01	12.12.01	Change accepted	-	-	12
Renewal of the Marketing Authorisation	R	08.10.01	13.12.01	Accepted	I, II, IIIA, IIIB	22.03.02	13
Change(s) to the test method(s) and/or specifications for the finished product	II	26.11.01	25.04.02	Change accepted	-	30.04.02	14

[1] T: Transfer of a Marketing Authorisation in accordance with Commission Regulation (EC) No 2141/96 of 7 November 1996.
I, II, I/II: In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended: I refers to a minor variation (type I variation); II refers to a major variation (type II variation); I / II refers to a minor variation following the procedure set out in Article 6, 7 and 8 of the Regulation.