Procedural steps taken and scientific information after the authorisation
Changes made after 01/07/1999

Forcaltonin

For procedures finalised before 01/07/1999, please refer to module 8A

MAJOR CHANGES[1]

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
R/0014	Renewal of the marketing authorisation	16/03/2005	04/07/2005	SPC, Labelling, PL	The safety and efficacy continue to be adequately and sufficiently demonstrated and the benefit/risk balance remains positive. Based on the currently available quality-related information relating to the approval of the new manufacturing site in the EU (see II/0013), the suspension of the Marketing Authorisation for Forcaltonin 100IU solution for infusion has been lifted.
II/0013	Change(s) to the manufacturing process for the finished product	20/01/2005	04/07/2005	PL	
Z/0012	Suspension	17/12/2003	14/04/2004		The CHMP concluded within the Renewal procedure that the MAH has failed to identify an authorised manufacturer to ensure the quality of the medicinal product and therefore recommends the suspension of the Marketing Authorisation for forcaltonin 100IU solution for injection according to Article 18 of Regulation 2309/93 of 22 July 1993. The opinion will be revisited after one year or as soon as all adequate information on the manufacturer of the finished product has been provided to the Committee.
II/0009	Update of or change(s) to the pharmaceutical documentation	21/02/2002	18/03/2002		

[1] Major changes e.g. Type II variations, Annex II applications, Renewals and Annual Reassessments
[2] SPC (Summary of Product Characteristics), Labelling, PL (Package Leaflet)

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
II/0002	Extension of Indication Extension of Indication. To include "prevention of acute bone loss due to sudden immobilisation such as in patients with recent osteoporotic fractures".	18/12/2002	11/06/2003	SPC, PL	Subsequent to the resolution of the Community Referral Procedure (EMEA/H/A-12/359) relating to calcitonin products.

MINOR CHANGES[3]

No	Scope	Product Information affected[2]	Date[4]
IA/0015	01_Change in the name and/or address of the marketing authorisation holder	SPC, Labelling, PL	19/10/2005
I/0010	Extension of shelf-life as foreseen at time of authorisation		21/07/2003
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	PL	25/10/2000
I/0007	Change in in-process controls applied during the manufacture of the product		27/07/2000
I/0006	Minor changes in manufacture of the medicinal product		27/07/2000
I/0005	Extension of shelf-life as foreseen at time of authorisation		26/06/2000
I/0004	Extension of shelf-life as foreseen at time of authorisation	SPC	26/06/2000
I/0003	Change following modification(s) of the manufacturing authorisation(s)		26/05/2000

[3] Minor changes e.g. Type I variations and Notifications
[4] Date of entry into force of the change