STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

- In March 1998, the Marketing Authorisation Holder submitted a request to the European Commission to change the spelling and wording of the Spanish labels and package leaflet to bring them more into line with the English text as adopted in the CPMP Opinion. The Commission approved the changes by means of a Corrigendum adopted on 26 March 1998.
- Pursuant to Article 10(3) of Council Directive 92/27/EEC of 31 March 1992, the Marketing Authorisation Holder notified the EMEA on 18 February 1999 of their intention to introduce changes to aspects of the labelling not connected to the Summary of Product Characteristics (changes in contact details of locan representatives in the Package Leaflet). The EMEA approved this Notification on 24 February 1999.
- On 3 March 1999, the Marketing Authorisation Holder submitted to the EMEA three applications for Type I variations. The EMEA approved these variations on 31 March 1999. The applications related to:

  1. A change in the name of a contract manufacturer of the finished product.
  2. A minor change of manufacturing process of the active substance.
  3. Minor changes in the manufacture of the medicinal product.

Subsequent post Marketing Authorisation applications agreed upon are summarised in the table below:

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Extension of Indication (as an adjunct to MRI to aid in the investigation of focal pancreatic lesions)	II/06	II	14.12.00	26.03.01
Change in shelf-life specification of Teslascan	II/07	II	21.02.02	12.06.02
Change in the name of the manufacturer of the active substance	I/08	I	18.10.01	05.11.01
Change in the name and address of the MAH and the manufacturer of the finished product	I/09	I	11.01.02	19.02.02
Renewal	R/10	R	21.03.02	18.06.02

[1] 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; **X** refers to an Annex II application.
T refers to a transfer of a Marketing Authorisation in accordance with Commission Regulation (EC) No 2141/96 of 7 November 1996.
N refers to a notification in accordance with Article 10(3) of Council Directive 92/27/EEC of 31 March 1992.

[2] For Notifications and Type I variations, the date of entry into force of the change is the EMEA Notification date. The Commission Decision will be amended accordingly.