

STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 March 2004 please refer to module 8B.

- On 5 May 1998 the company's proposals to include a diagram summarising the conduct of the diagnostic test on the inner surface of the outer pack was approved by means of a Notification under Article 10(3) of Council Directive 92/27/EEC.
- On 11 June 1999 the marketing authorisation holder's request to change the local contact addresses in the package leaflet by means of a Notification under Article 10(3) of Council Directive 92/27/EEC was approved.

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
Minor change in labelling or package leaflet not connected with the SPC (Art. 10.3 Notification)	N/0003	N	27.01.00	24.05.00
Change in the name of a manufacturer of the active substance	I/0004	I	18.02.00	14.05.00
Minor change in labelling or package leaflet not connected with the SPC (Art. 10.3 Notification)	N/0005	N	05.06.00	11.07.00
Extension of the indication to adolescents (aged 12-17 years)	II/006	II	18.10.01	23.04.02
Additional presentation of the product, containing flexible aluminium bags, suitable for interfacing with nondispersive infrared (NDIR) spectrometers.	II/007	II	17.01.02	02.05.02
Line extension for use in children (aged 3-12 years)	X/008	X	27.06.02	10.10.02
Renewal	R/009	R	27.06.02	29.10.02
Change in pack size - change in no. of units outside range of appr. pack size	IB/010	IB	27.02.04	-

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.