STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

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

- On 8 January 1999, the Marketing Authorisation Holder submitted to the EMEA an application for Micardis 20 mg tablets, under Annex II to Commission Regulation (EC) 542/95 as amended. The CPMP recommended the approval for this additional strength and adopted an opinion on 20 May 1999. The respective Commission Decision was issued on 7 September 1999.
- Pursuant to Article 10(3) of Council Directive No. 92/27/EEC of 31 March 1992, the Marketing Authorisation Holder, notified the EMEA on 26 February 1999 of their intention to introduce changes to an aspect of the labelling not connected to the Summary of Product Characteristics. The Company requested additional changes on 8 March and 27 April 1999. (Changes to the Austrian contact address and the Danish contact fax number have been introduced. The section "Storage conditions" of the package leaflet has been amended in order to be consistent with the section "Special precautions for storage" of the SPC. Linguistic corrections have been implemented into the German and Greek package leaflet.). On 30 April 1999, the EMEA hereby informs the European Commission that the above-mentioned changes are accepted. The respective Commission Decision was issued on 03 June 1999.
- The Marketing Authorisation Holder submitted to the EMEA on 8 March 1999 an application for one type I variation falling within the scope of item No. 15 of Annex I to Commission Regulation (EC) No 542/95, as amended. The Marketing Authorisation Holder applied for:

  Several minor changes to the manufacturing process of the finished product, including an increase in batch size.

  On 19 April 1999, the EMEA approved the variation. This variation did not require amendments to the Commission Decision.
- The Marketing Authorisation Holder submitted to the EMEA on 8 March 1999 an application for one type I variation falling within the scope of item No. 1 of Annex I to Commission Regulation (EC) No 542/95, as amended. The Marketing Authorisation Holder applied for:

  A change in the sites of the manufacture of spray dried granulates.

  On 19 April 1999, the EMEA approved the variation. This variation did not require amendments to the Commission Decision.
- The Marketing Authorisation Holder submitted to the EMEA, between 6 September 1999 and 19 November 1999, a number of applications for one type I variation falling within the scopes of item No 1, 12a, 14, 24a and 32 of Annex I to Commission Regulation (EC) No 542/95, as amended. The Marketing Authorisation Holder applied for:

- Change of the manufacturing sites for part of the manufacturing process of the medicinal product,
- Change of imprints, bossing or other markings (except scoring) on tablets.
- Change in specification of starting material or intermediate used in the manufacture of the active substance (with Change in specification of active substance).
- Changes in test procedure for starting material or intermediate used in the manufacture of the active substance.

  Between 29 October 1999 and 15 March 2000, the EMEA issued the corresponding notifications. These variations did not require amendments to the Commission Decision.

- The Marketing Authorisation Holder submitted to the EMEA on 8 November 1999 an application for one type I variation falling within the scope of item No 20 of Annex I to Commission Regulation (EC) No 542/95, as amended. The Marketing Authorisation Holder applied for:

An extension of shelf-life.

On 17 December 1999, the EMEA issued the corresponding notification. The variation required amendments in the relevant sections of the Commission decision. The respective Commission Decision was issued on 09 March 2000.

- Pursuant to Article 10(3) of Council Directive No. 92/27/EEC of 31 March 1992, the Marketing Authorisation Holder, notified the EMEA on 9 February 2000 of their intention to introduce changes to an aspect of the labelling of the 20 mg strength not connected to the Summary of Product Characteristics. Changes were related to the list of Marketing Authorisation representatives or were of linguistic nature. On 21 February 2000, the EMEA issued the corresponding notification. The respective Commission Decision was issued on 30 March 2000.

- On 31 January 2000, the Marketing Authorisation Holder submitted a Type II variation application in accordance with Article 6 of Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended. The scope of the variation related to the update of the SPC and PL of the 40 and 80 mg strengths to put them in line with the SPC and PL of the recently approved 20 mg strength and with the latest QRD SPC/labelling/PL templates. In addition, the list of local representatives of the Marketing Authorisation Holder in the Package Leaflet has been updated. During the assessment, sections on pregnancy and interaction with food have been revised in order to be more accurate.

  On 12 April 2000, the CPMP approved the variation. The variation required amendments in the relevant sections of the Commission Decision and the EPAR. The European Commission amended the Decision on 1 August 2000.

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 of manufacturing process of the active substance With consequential change in test procedure for starting material/intermediate used in manuf. of active substance	I/0016	I	02.08.00	N/A
Batch size of active substance	I/0017	I	02.08.00	N/A
Change in test procedures of the medicinal product	I/0018	I	15.08.00	N/A
Changes in manufacture of the medicinal product	I/0019	I	22.09.00	N/A
Update of Summary of Product Characteristics and Package Leaflet The SPC was updated following the assessment of the 2nd and 3rd PSUR.	II/0020	II	19.10.00	22.01.01
Replacement of an excipient with a comparable excipient	I/0021	I	04.05.01	-
Extension of shelf-life as foreseen at time of authorisation	I/0022	I	22.08.01	19.10.01
Change in pack size for a medicinal product	I/0023	I	23.08.01	19.10.01
Update of Summary of Product Characteristics and Package Leaflet	II/0024	II	21.02.02	30.05.02
Change in the name of a manufacturer of the medicinal product	I/0026	I	23.05.02	24.05.02

[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.