Steps taken after granting the Marketing Authorisation

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

- On 30 August 1996 the Marketing Authorisation Holder submitted an application for two variations (Type I) relating to changes in the manufacture and changes in test procedures of the medicinal product. The procedure started on 12 September 1996. These variations were approved by the EMEA on 11 October 1996 and did not require any amendments to the Commission Decision. Changes were introduced in the chemical, pharmaceutical and biological documentation of the dossier. The section III.2 of this EPAR has been amended accordingly.
- On 17 July 1996 the CPMP adopted a positive Opinion on an application for an extension of the Marketing Authorisation to a new strength (2 mg/2 ml) for Bondronat submitted by the Marketing Authorisation Holder. The European Commission on 25 October 1996 issued a favourable Decision.
- On 11 March 1997 the Marketing Authorisation Holder submitted an application for a Type II variation in connection with addition of a pack size of 1 ampoule to the already approved pack size of 5 ampoules. The CPMP adopted a positive Opinion on 16 April 1997. The European Commission on 27 August 1997 issued a favourable Decision.
- On 21 May 1998 the Marketing Authorisation Holder submitted an application for a Type I variation relating to changes in the specifications and test procedures of the active substance. The procedure started on 29 May 1998. This variation was approved by the EMEA on 10 June 1998 and did not require any amendments to the Commission Decision. Changes were introduced in the chemical, pharmaceutical and biological documentation of the dossier.
- On 20 November 1998 the Marketing Authorisation Holder submitted two applications for two Type I variations relating to changes in the test procedures of the medicinal product. The procedure started on 27 November 1998. The variations were approved by the EMEA on 18 December 1998 and did not require any amendments to the Commission Decision. Changes were introduced in the chemical, pharmaceutical and biological documentation of the dossier.
- On 12 January 1999 the Marketing authorisation Holder submitted an application for the transfer of the Marketing Authorisation for Bondronat from Boehringer Mannheim GmbH to Roche Registration Limited, United Kingdom. The transfer was approved by the EMEA. The EMEA notified the European Commission, who amended the Commission Decision on 29 March 1999.
- On 12 January 1999 the Marketing Authorisation Holder submitted an application for a Type I variation relating to changes in the name of the manufacturer of the medicinal product and subsequent change in the name of the manufacturer of the active substance. The procedure started on 26 January 1999. The variation was approved by the EMEA on 9 February 1999. This variation required amendments in the relevant sections of the Commission Decision. The European Commission amended the Decision on 11 May 1999.
- On 19 July 1999 the Marketing Authorisation Holder submitted an application for a Type I variation for a change in the shelf-life of the medicinal product. The procedure started on 19 July 1999. The variation was approved by the EMEA on 5 August 1999. This variation required amendments in the relevant sections of the Commission Decision. The European Commission amended the Decision on 16 November 1999.
- In accordance with Article 10(3) of Council Directive 92/27 EEC of 31 March 1992, the EMEA issued on 5 August 1999 a Notification for amendment of the addresses of the local representatives included in the package leaflet as applied for by the MAH. The Commission amended the Commission Decision on 16 November 1999.
- On 10 April 2000 the Marketing Authorisation Holder submitted a Corrigendum to the Commission Decision dated 16 November 1999 for the Dutch SPC (section 4.3), Finnish SPC (section 6.4) and Portuguese SPC (section 5.2). This Corrigendum required amendments to the relevant sections of the Commission Decision. The European Commission amended the Decision on 11 August 2000.
- In accordance with Article 10(3) of Council Directive 92/27 EEC of 31 March 1992, the EMEA issued on 10 May 2000 a Notification for amendment of the Greek and Portuguese addresses of the local representatives included in the package leaflet as applied for by the MAH. A change has also been made to the Spanish version in which the strength mentioned in section 5 of the Package Leaflet has been corrected from 1 mg/ 1 ml to 2 mg/ 2 ml. The Commission amended the Commission Decision on 27 June 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
Change in pack size for a medicinal product	I/16	I	23.02.01	23.04.01
Extension new strength	X/17	X	29.03.01	13.09.01
5-year Renewal of the Marketing Authorisation	R/18	R	25.04.01	12.09.01
Update of Summary of Product Characteristics sections 4.6 and 5.3	II/19	II	25.04.01	12.09.01
Update of Summary of Product Characteristics sections 4.5 and 5.2 and Package Leaflet section 2	II/20	II	25.04.01	12.09.01
Change in test procedures of the medicinal product	I/21	I	30.08.02	10.09.02
Extension of Indication	II/22	II	24.07.03	07.11.03
Addition of a new pharmaceutical form	X/23	X	24.07.03	24.10.03
New presentation(s)	II/25	II	24.07.03	31.10.03
Change in shelf-life of finished product - as packaged for sale	IB/26	IB	12.01.04	-
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/27	N	30.03.04	-
Change in shelf-life of finished product - as packaged for sale	IB/31	IB	17.06.04	-

[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.