## STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 21 March 2002 please refer to module 8B.

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 |
|---|---|---|---|---|
| Transfer of Marketing Authorisation Holder | T/0001 | T | 24.01.01 | 21.03.01 |
| Validation process of the dry heat block | II/0002 | II | 16.11.00 | 21.03.01 |
| Change in specification of excipients in the medicinal product (excluding adjuvants for vaccines) | I/0004 | I | 19.09.01 | N/A |
| Change in source of doxirubicin | II/0005 | II | 20.09.01 | 21.03.02 |
| Change in shelf life after reconstitution | I/0006 | I | 28.02.02 | 12.04.02 |
| Change following modification(s) of the manufacturing authorisation(s) | I/0007 | I | 25.11.02 | 18.12.02 |
| Change in test procedures of the medicinal product | I/0008 | I | 08.01.03 | 13.01.03 |
| Change in test procedures of the medicinal product | I/0009 | I | 12.02.03 | 26.02.03 |
| Change in test procedures of the medicinal product | I/0010 | I | 08.01.03 | 13.01.03 |
| Change in test procedures of the medicinal product | I/0011 | I | 14.01.03 | 21.01.03 |
| Change in test procedures of the medicinal product | I/0012 | I | 14.01.03 | 21.01.03 |
| Change in the name of a manufacturer of the medicinal product | I/0013 | I | 23.04.03 | 02.05.03 |

[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.