

STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 July 1999, please refer to module 8B.

- The applicant agreed to submit additional information regarding chemical, pharmaceutical and biological data within the defined timeframe. Furthermore, a 10 (3) notification of a change to an aspect of the Labelling and the Package Leaflet not connected to the Summary of Product Characteristics was adopted on 23 April 99 and the relevant Commission Decision was issued on 3 June 1999.

Medicinal product no longer authorised