

STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION:

For procedures finalised after 1 October 2001 please refer to module 8B

- Between September 1998 and April 2000, three Type I variations were submitted, seeking to add an additional packaging (assembly) site for the finished product. The latest of these (I/03) was approved by a Notification to the applicant dated 14 April 2000.
- The Marketing Authorisation Holder applied on 10 October 2000 for a change of address for one of the assembly (packaging) sites for Pylobactell which was also a site where testing takes place. The manufacturer responsible for batch release in the European Economic Area remained unchanged. The change (I/04) was approved by a Notification to the applicant dated 27 October 2000.
- The Marketing Authorisation Holder applied on 27 November 2000 to change the name and address of the Marketing Authorisation Holder for Pylobactell, BSIA Limited, to Cambridge Export No. 2 Limited. The change (I/05) was approved by a Notification to the applicant dated 19 December 2000. The revised annexes I, II and III were annexed to this notification, and the revised Commission Decision in all EU languages was issued on 5 March 2001.
- The Marketing Authorisation Holder applied on 27 November 2000, to delete a site of assembly/batch release, site of storage/distribution and manufacturer responsible for batch release in the EEA, and to add another site of storage/distribution, and as the manufacturer responsible for batch release in the EEA. The change (I/06) was approved by a Notification to the applicant dated 19 December 2000. The revised annexes II and IIIB were annexed to this notification, and the revised Commission Decision in all EU languages was issued on 5 March 2001.
- The Marketing Authorisation Holder applied on 31 January 2001 to transfer the Marketing Authorisation for Pylobactell to Torbet Laboratories, Ltd. Limited. The EMEA issued a Notification on the transfer (T/07) on 6 July 2001 The revised annexes I, II and III were annexed to this notification, and the revised Commission Decision in all EU languages was issued on 17 September 2001.