



e-form

Batch Specific Requests Application Form



1 Name and address of the Marketing Authorisation Holder:

Telephone:

E-mail:

2 Name and address of applicant (if different from 1. above, where applicable) – letter of consent from Marketing Authorisation Holder to make request should be attached with the application:

Telephone:

E-mail:

3 Product details:

3.1 MA number(s):

3.2 Strength(s):

3.3 Pharmaceutical form(s):

3.4 Name of product(s):

4 Details for requested variation:

4.1 Reason for request to supply batches:

4.2 Justification for supply batches:

4.3 Expected duration of supply (maximum 6 months):

4.4 Number of units:

4.5 Batch number(s):

5 Details of the changes requested:

5.1 Is the product(s) manufactured and packaged under the same conditions as those approved under the above MA(s)?

If no, please specify the differences:

5.2 Are the label (outer package) and leaflet texts the same as those approved under the relevant MA(s)?

If no, attach copies of the approved MA full colour mock-ups (or copies in colour) and the texts for the product(s) to be supplied. Highlight the differences.

5.3 If any packaging operation is proposed indicate the name and address of the manufacturing site(s) at which this will be carried out and attach the manufacturing authorisation(s), if outside Malta:

If in Malta, include GMP licence number:

Name of applicant:

Status (job title):

Signature of applicant: