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):**

**3.2Strength(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 3 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:**

Kindly fill in the Declaration form at the following link http://www.medicinesauthority.gov.mt/onlineapplications
A Declaration form should be submitted for each signatory.







