Batch-Specific Requests for Veterinary Medicines

For details of the requirements, please see the ‘Guide to Batch-Specific Requests for Veterinary Medicines’. If the request refers to multiple Marketing Authorisations (MAs), refer to specific VPAs throughout where appropriate.

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| Name and address of MA holder: | Name and address of applicant, if different:    Attach letter of consent from MA holder for applicant to make request.  Email contact details: | |
| MA number(s):  Strength(s):  Pack sizes: | Brand name of product:  Pharmaceutical form: | |
| Reason for request to supply batches:  Justification for supply of batches:  Has a similar request for this product or related products (different strengths, forms or pack sizes) been made in the past twelve months?  No  Yes  If yes, indicate HPRA case reference number:  Expected duration of supply:  Number of units:  Batch number(s):       (must be provided later if not known at the time of the request) | | |
| Is the product manufactured and packaged under the same conditions as those approved under the above MA?  Yes  No  If no, specify in detail the differences: | | |
| Are the label and insert texts the same as those approved under the relevant MA?  Yes  No  If no, attach copies of the approved VPA mock-ups and the mock-ups of the product to be supplied including samples of proposed over-label, if applicable. Highlight the differences. | | |
| If any packaging operation is proposed, or is deemed necessary by the HPRA, indicate the name and address of the manufacturing site at which this will be carried out and attach the manufacturing authorisation if outside Ireland or provide the relevant Eudra GMP reference.[[1]](#footnote-1)  Name of company:  Address:  Eudra GMP reference: | | |
| Name of HPRA staff member with whom this request has been discussed: | | |
| Name of applicant:  Signature of applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Status (job title):  Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

Send to:

Receipts and Validation Section

Health Products Regulatory Authority

Kevin O’Malley House

Earlsfort Centre, Earlsfort Terrace

Dublin 2

D02 XP77

Or email to [submissions@hpra.ie](mailto:submit@hpra.ie)

Tel: +353 1 6764971

Fax: +353 1 6767836

1. If rubber-banding of documentation (e.g. a Package Leaflet or a Caution-in-Use Letter) to the outer pack of the product, or the insertion of product into a sleeve/plastic bag, etc., with additional information (such as the PL or CIU letter) in it has been approved, the rubber banding/insertion operation does not need to be carried out at an authorised manufacturer under GMP, as the packs are not being opened or reassembled. However, those operations need to be performed at an authorised wholesaler and details of the site(s) should still be stated. [↑](#footnote-ref-1)