Batch-specific Requests

For details of the requirements, please see the Guide to Batch-Specific Requests for Human Medicines. If the request refers to multiple MAs, refer to specific MAs throughout where appropriate.

|  |  |
| --- | --- |
| Name and address of MA holder(s):      Direct telephone number:      Email:       | Name and address of applicant (if different):      Direct telephone number:      Email:      *Attach letter of consent from MA holder(s) for applicant to make request.* |
| PA/EU/TR/HOA/HOR number(s):      Strength(s):       | Brand name of product(s): Pharmaceutical form(s):  |
| Urgent request? Yes [ ]  No [ ] If urgent, please justify reason for urgency:       |

|  |  |
| --- | --- |
| Is the product imported from outside the EU/EEA or from Northern Ireland? | Yes [ ]  No [ ]  |
| If yes, specify the country of origin |       |

|  |  |
| --- | --- |
| Reason for, and details of, the request to supply batches (including information on the nature of any non-compliance / quality defect issue) |       |
| * Justification for supply of batches: an explanation of the public health impact if there was an interruption to supply including whether the product is a critical/essential medicinal product and whether alternative products or presentations are available, current stock levels and the projected duration of supply
 |       |
| * Specify whether this is an actual or a potential Out Of Stock situation and its implications for patients
 |       |
| Repeat BSR for above specified product? | Yes [ ]  No [ ]  | If yes, indicate previous HPRA case number(s):  |
| Has a similar request for related products (different strengths or forms) been made in the past twelve months? | Yes [ ]  No [ ]   | If yes, indicate previous HPRA case number(s):  |
| Expected duration of supply |  *Should be no more than three months. Specific justification should be provided for any supply in excess of three months.* |
| Number of units |       |
| Batch number(s) | *Must be provided later if not known at time of request.* |

|  |  |  |
| --- | --- | --- |
| Is the product(s) manufactured, packaged, QC tested and QP released under the same conditions as those approved in as the Irish/ EU authorised MA(s)? | Yes [ ]  No [ ]  | If no, specify in detail the differences:  |
| Are the label and leaflet texts the same as those approved under the relevant MA(s)? | Yes [ ]  No [ ]  | *If no, attach copies of the approved MA full colour mock-ups and the texts for the product(s) to be supplied. Highlight the differences.* |
| Is the product compliant with the Falsified Medicines Directive 2011/62/EU?  | Yes [ ]  No [ ]  | If no, please include justification:  |
| Have the serialisation data for the batch in question been uploaded into the relevant safety features repository? | Yes [ ]  No [ ]  | If no, please include justification:  |
| Do packs have an anti-tampering device on their outer packaging? | Yes [ ]  No [ ]  | If no, please include justification:  |

|  |
| --- |
| If any packaging operation is proposed, or is deemed necessary by the HPRA, indicate the name and address of the manufacturing or wholesaler site(s) at which this will be carried out and attach the wholesaler or manufacturing and import authorisation(s), if outside Ireland. A copy of the manufacturing and import authorisation(s) must be submitted.[[1]](#footnote-2)  |
| Name(s) and address(es) of the manufacturing site(s): Manufacturing and import authorisation(s) included: [ ] Name(s) and address(es) of the wholesaler site(s): Wholesaler authorisation(s) included: [ ]  |

|  |
| --- |
| Name of HPRA staff member with whom this request has been discussed:  |
| Name of applicant: Status (job title):  | Signature of applicant:Date:       |

Send to or email to:

Receipts and Validation

Health Products Regulatory Authority

Kevin O’Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

D02 XP77

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

Email: submissions@hpra.ie

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 under the supervision and oversight of the Responsible Person, so details of the site(s) should still be stated. [↑](#footnote-ref-2)