

**Batch specific request for exemptions from the requirements of article 54(o) and 54a of Directive 2001/83/EC and Regulation (EU) 2016/1612 (FMD requirements) \* for use by CPSU**

Send signed and scanned applications to mailbox: licensing.medicinesauthority.gov.mt or via the CESP

**\**For batches released after 9 February 2019 without safety features***

# PART I – To be filled in by the supplier/wholesale dealer

# Product details:

3.1 Name of product(s):

3.2 MA/AA/PI number(s):

3.3 Strength(s):

3.4 Pharmaceutical form(s):

# Name and address of the Authorisation Holder or Parallel Importer:

Telephone:

E-mail:

# Name and address of applicant (if different from 1. above, where applicable) – (letter of authorisation from authorisation holder to make request should be attached with the application)

Telephone:

E-mail:

# Details of the changes requested:

4.1 Excluding the introduction of the safety features, is the product(s) manufactured and packaged under the same conditions as those approved under the above MA(s)/licence(s)?

Yes  - If Yes, continue to Sections 5

No  - If No, continue to Section 4.2 If no, please specify the differences:

4.2 Are the label (outer and inner package) and leaflet texts the same as those approved under the relevant MMA(s)/licence(s), excluding the absence of safety features as required by article 54?

Yes  - If Yes continue to 4.3

No  - If No, continue to 4.3

4.3 If any packaging operation is proposed as a result of 4.1 and 4.2, indicate:

The name and address of the manufacturing site(s)at which this will be carried out . Include the manufacturing authorisation(s) and/or GMP licence number and/or EudraGDMP document reference number.

1. **Name and address of the wholesale dealer bringing in the product to Malta:**

Telephone:

E-mail:

1. **Plan (with timeframe) for future batches to be in line with FMD:**

Information should be provided regarding the process for ensuring that the product will be in line with the requirements of the FMD, including planned timeframe.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| **Name of signatory:**  **Status (job title)**:  **Date**:  **Signature**: |  |

# Part II – To be filled in by CPSU

# Details for requested exemption

* 1. Justification for suppling batches without FMD:
  2. Number of units:
  3. Batch number(s):

7.4 Is this a repeat BSR for this same exemption? Yes  No

7.4.1 – Provide justification why a repeat BSR was submitted as opposed to procuring the medicinal product in line with FMD as mentioned in the last BSR application form

7.5 Is request urgent?

Yes  No

If Yes, please state reason:

1. **Distribution details:**

The units will be distributed to:

POYC

MDH

Other (specify):

Please attach detailed plan of how the units will be distributed in Annex 3. The units mentioned in the plan must tally with the section 5.3

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| --- | --- |
| **Name:**  **Status (job title):** | **Signature of CPSU**  **Date:** |

**Annex I**

– Letter of authorisation from MAH/AAH to make a request for exemption *(only if applicable; attach signed copy)*

**Annex 2**

**Declaration by CPSU**

I declare that this exemption is being requested after I have done my due diligence in trying to source a product that is fully compliant with the legislation, including the inclusion of the safety features as required by Directive 2001/83/EC.

I declare that this product is critical, and I have carried out a risk-based assessment on the public health impact if there had to be an interruption in supply for this product.

I attach a distribution plan (Annex 3) for this consignment of the product.

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| --- | --- |
| Name:  Status (job title): | Signature:  Date: |

**Annex 3**

**CPSU distribution plan for this consignment (please list or attach)**

|  |  |
| --- | --- |
| Name:  Status (job title): | Signature:  Date: |