e-form

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 via the CESP

*** N.B Exemptions relate to batches not bearing the FMD features; anti-tampering device and unique identifier**

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

1. Product details:

1.1 Name of product(s):

1.2 MA/AA/PI number(s):

1.3 Strength(s):

1.4 Pharmaceutical form(s):

2. Name and address of the Authorisation Holder or Parallel Importer:

Telephone:

E-mail:

3.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:

4. Details of the changes requested:

5. Name and address of the wholesale dealer placing the product on the market in Malta:

Name and address:	
Telephone:	
E-mail:	

6. 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.

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

PART II - To be filled in by CPSU

7. Details for requested exemption

7.1 Justification for supplying batches without FMD:

7.2 Number of units:

7.3 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:

8. Distribution details:

The units will be distributed to:

- [ ] **POYC**
- [ ] **MDH**
- [ ] **Other (specify):**

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

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.

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