In order for the MAH/AAH (who must be established in the Union), to apply to Malta for this **time limited conditional exemption**, please provide the information requested in the form attached to the Medicines Authority, for the evaluation of your request (no later than 30th Jan 2021). Approval of this request will be primarily based on the information provided and the conditions agreed to by the applicant in this form, which should be carefully completed.

Requests for exemptions by the Medicines Authority only applies to medicinal products supplied to the Maltese market.

The exemptions are limited in time and will expire no later than 31st December 2021.

The exemptions relating to batch release and Quality Control (QC) testing are intended to allow these activities to continue for a short period of time at currently registered sites in Great Britain to facilitate supply of medicines **while these functions are being transferred to sites in the Union** or Northern Ireland.

Please note that these exemptions may not generally be availed of where the specific functions have already been transferred to EU/EEA sites.

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Acceptance of any requests for exemptions by the Medicines Authority only applies to medicinal products supplied to the Maltese market being carried out in Malta. The exemptions are limited in time and will expire no later than 31st December 2021.

**NOTES:**

* **Section A** must be completed for ALL requests
* **Section B (including subsections and associated condition sections)** completed for the specific exemptions, which are requested.
* One application form is required for **each product (all strengths combined).** Where possible, all exemption requests applicable to the same product should be contained within the same form.
* Please note that as per European Commission Notice there is a commitment to provide to the Medicines Authority a monthly update on progress towards compliance for these activities.
* This monthly update should include a track changed version of the ‘timeline and pathway’ information provided in Section B.1, B.2, B.3 and B.4.

1. Section A: Administrative details

With reference to the published communication from the EU Commission dated 22nd December 2020, we hereby request a time-limited exemption to continue to supply the following medicinal product or investigational medicinal product to the Maltese market:

## Product specific details for Malta

|  |  |  |  |
| --- | --- | --- | --- |
| Invented name of medicinal product/INN | MA/AA Number | DCP/MRP procedure number, if applicable: | Marketing authorisation holder name and address |
|  |  |  |  |

The following situation applies for the above product: *(tick ‘yes’ or ‘no’ to indicate which case applies)*:

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| It will be imported into Malta under a Wholesale Distribution Authorisation (WDA) rather than a Manufacturers Authorisation (if ‘yes’, *complete section B.1 of form*) |  |  |
| Quality control tests will be conducted in GB (*if yes,* *complete section B.2 of form*) |  |  |
| Batch release will take place in GB (*if yes,* *complete section B.3 of form*) |  |  |
| It will be imported through GB in its non-decommissioned status (*if* ***yes****,* *complete section B.4 of form*) |  |  |

*Complete Sections B.1, B.2, B.3 and/or B.4 of form as applicable and the associated commitments sections (B.1.1 or B.1.2)*

End date of the requested exemption: **\_\_\_\_Date/Month/2021**

1. Section B: Notification of request:

## B.1: To import a medicine into Malta under a Wholesale Distribution Authorisation

|  |
| --- |
| *Name and address and WDA number of the current Maltese wholesaler accepting product from GB:*  *Name and address of the proposed EU site for future physical importation:*  *Timeline and pathway for obtaining/using an MIA for the proposed EU site of importation:*  *Concise justification of the timeline required:* |

**Confirmation of compliance with conditions to permit importation of a medicinal product into Malta under a Wholesale Distribution Authorisation**

**(Section B.1):**

*Please confirm all of the following by using the tick-boxes:*

**Medicinal products confirmation:**

We herewith declare that:

The medicinal products supplied from or through Great Britain and placed on the Maltese market in accordance with Union law (i.e. imported into the Union or Northern Ireland) have undergone quality control testing (‘batch testing’) either in the Union, as provided for in Article 51(3) of Directive 2001/83/EC, or in Great Britain in compliance with Article 20 (b) of Directive 2001/83/EC for human medicinal products

The medicinal products supplied from or through Great Britain and placed on the market in Malta in accordance with Union law (i.e. imported into the Union or Northern Ireland) have been subject to batch release by a Qualified Person (QP) in the Union or by a QP in the UK applying equivalent quality standards to those laid down in Union law, thus ensuring an equivalent level of protection of human health;

The operator placing medicinal products supplied from or through Great Britain on the market in Malta in accordance with Union law (in the Union or in Northern Ireland) holds a distribution authorisation issued, before the end of the transition period, in accordance with Article 77(1) of Directive 2001/83/EC for human medicinal products;

The marketing authorisation of the medicinal product concerned has been issued by the competent authority of an EU Member State, by the Commission, or by the competent authority of the United Kingdom before the end of the transition period (31st December 2020) and in accordance with Union law;

The medicinal products supplied through Great Britain are made available to the end consumer in Malta, and they are not made available in other EU Member States;

We will provide by 20th of each month a monthly update on the progress made to conduct physical importation under a manufacturer’s authorisation relating to the site where this activity will occur.

**On behalf of the Wholesale Distributor/MIA holder:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature and printed name of the authorised contact person*

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## B.2: To permit continued QC testing in GB

|  |
| --- |
| *Name and address of the* ***currently registered*** *QC testing site in GB to be used:*  *EudraGMDP or MHRA reference number of QC testing site in GB:*  *Name and address of the* ***proposed*** *EU site of QC testing:*  *Timeline and pathway for transfer and registration of the proposed EU site of QC testing, (Include also cases where a variation to add an EU testing site has been recently submitted, but is not yet reflected in the MA. Please indicate the procedure number for introducing the site in the MA (where available) or if the variation is not yet submitted included, the planned submission date):*  *Concise justification of the timeline required:*  *EudraGMDP reference number of EU QC testing site if available:*  *Name and address of the currently registered batch release site to be used:*  *EudraGMDP reference number of manufacturing authorization of the batch release site:* |

*Note: Please copy the above table in case of multiple QC testing sites*

**Confirmation of compliance with conditions to permit batch testing of human or veterinary medicinal products in Great Britain (Section B.2)**

(*please confirm all of the following by using the tick-boxes*):

We herewith declare that:

The Qualified Person(s) of the batch release site(s) indicated above in EU/EEA, UK NI or UK GB is/are responsible for ensuring that the quality control testing at the site(s) in GB is conducted in accordance with EU GMP and the requirements of the Marketing Authorisation;

The establishment conducting the quality control testing is supervised by a competent authority, including on-the-spot checks;

The medicinal products imported from Great Britain are made available to the end consumer in Malta only, and they are not made available in other EU Member States;

☐ We have taken necessary steps to prepare for transfer of the quality control testing and the transfer will be complete by the end of Dec 2021 at the latest;

We will provide a monthly update by 20th of each month on the progress made to ensure that testing is conducted at approved sites within the EU.

**On behalf of the MAH/AAH:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature and printed name of the authorised contact person*

Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## B.3: To permit continued batch release in GB

|  |
| --- |
| *Name and address of the* ***currently registered*** *batch release site in GB to be used:*  *EudraGMDP reference or MHRA reference number of manufacturing authorisation for current site:*  *Name, address of the* ***proposed*** *EU site of batch release*  *EudraGMDP reference number of manufacturing authorisation or GMP certificate, if available:*  *Timeline and pathway for registration of the proposed EU site of batch release. (Include also cases where a variation to add an EU batch release site has been recently submitted, but is not yet reflected in the MA. Please indicate the procedure number for introducing the site in the MA (where available) or if the variation is not yet submitted included, the planned submission date):*  *Concise justification of the timeline required:* |

***Note: Please copy the above table in case of multiple batch release sites***

**Confirmation of compliance with conditions to permit batch release of human or veterinary medicinal products in Great Britain (Section B.3)**

(*please confirm all of the following by using the tick-boxes*):

We herewith declare that:

The Qualified Person(s) of the batch release site(s) indicated above, UK NI or UK GB is/are responsible for ensuring that the batch release site applies equivalent quality standards to those laid down in Union law; with EU GMP and the requirements of the Marketing Authorisation;

The establishment conducting the batch control/release is supervised by a competent authority, including on-the-spot checks;

The medicinal products imported from Great Britain are made available to the end consumer in Malta only, and they are not made available in other EU Member States;

☐ We have taken necessary steps to prepare for transfer of the batch release and the transfer will be complete by the end of Dec 2021 at the latest;

We will provide a monthly update by 20th of each month on the progress made to ensure that release is conducted at approved sites within the EU.

**On behalf of the marketing authorisation holder/wholesale dealing licence holder:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature and printed name of the authorised contact person*

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## B.4: To permit the import of non-decommissioned stock into Malta through GB

|  |
| --- |
| *The MAH/wholesale dealing licence holder must report on a monthly basis to the Malta Medicines Authority with a position on the progress made by wholesale distributors importing medicinal products through Great Britain in fulfilling the obligations under Directive 2001/83 and Commission Delegated Regulation (EU) 2016/161 relating to placement of the unique identifier.* |

**Confirmation of compliance with conditions to permit the temporary removal of the obligation to decommission safety features applied to medicinal products supplied through Great Britain by a manufacturer, importer or wholesaler in the Union (Section B.4)**

(*please confirm all of the following by using the tick-boxes*):

We herewith declare that:

The wholesale distributor or the marketing authorisation holder established in the Union and responsible for the export of the medicinal product to the United Kingdom has verified the unique identifier against the European repository or the national repository system;

The wholesale distributor importing the product from Great Britain to Malta has verified the unique identifier against the European repository or the national repository system;

The wholesale distributor importing medicinal products from Great Britain to Malta, by reporting on a monthly basis to the Malta Medicines Authority, commits to demonstrate progress in fulfilling the obligations under Directive 2001/83 and Commission Delegated Regulation (EU) 2016/161 relating to placement of the unique identifier.

**On behalf of the MAH/AAH:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Signature and printed name of the authorised contact person*

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_