Notification of request for a time-limited exemption to continue batch control testing in the United Kingdom (UK) after UK's withdrawal from the Union for a centrally authorised medicinal product

Invented name of medicinal product: …

Product (EMEA) number: EMEA/…/C/00…

Product (EU) number: EU/…

Marketing authorisation (MA) holder name and address: …

With reference to the published communication from the European Commission dated 21/02/2019, we herewith request a time-limited exemption to continue batch control testing in the UK after 29 March 2019 for the above mentioned centrally authorised medicinal product with the following scope:

1. Identified batch release site(s) in EU27/EEA

Company name (batch release site): …
Address of the site: …
Country: …
EudraGMDP reference number of manufacturing authorisation: …
If the site has been recently added and is not yet reflected in published MA Annexes, please indicate the procedure number for introducing the site in the MA (where available) or planned imminent submission date: …

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

2. Current batch control site(s) in UK

Company name (batch control site in UK): …
Address of the site: …, UK
Finished product specification parameters tested at the site[1]: …

Note: Please copy the above table in case of multiple batch control sites in the UK

3. Timelines for implementation of the (new) batch control testing in the EU27/EEA

Name of the new EU27/EEA site for batch control testing for release: …

[1] Include only those tests that cannot be conducted in a (potential) already approved alternative testing site in EU27/EEA

Address of the site: … Country: … EudraGMDP reference number of manufacturing authorisation or GMP certificate (if available): … For biological products, finished product specification parameters to be tested at this site: …		
Activities for transfer of batch control testing	*Planned date of completion*	*Short justification for the time required*
<Specify main steps needed for transfer of testing. Include additional rows as needed.>	…	…
…	…	…
Implementation of testing at this site	**…**	…
For biological products: submission of respective variation application[2]	**…**	Planned variation type: …

Note: Please copy the above table in case multiple batch control sites in EU27/EEA will be used for the specifications/tests to be transferred.

End date of the requested exemption: …[3]

4. Confirmation

We herewith declare that (please confirm all of the following by using the tick-boxes):

☐ The Qualified Person(s) of the EU27/EEA batch release site(s) indicated above is(/are) established in EU27/EEA and is (/are) responsible for ensuring that the quality control testing at the site(s) in the UK is conducted in accordance with EU GMP and the requirements of the Marketing Authorisation;

☐ Upon request, we will provide to EMA and/or the relevant EU27/EEA national competent authorities batch testing results from the facilities within the UK for the batches to be released under this exemption;

☐ Test results will be provided to the Qualified Person(s) of the EU27/EEA batch release site(s) prior to certification and release of batches under this exemption. The associated reference / retention samples for these batches will, in due time, be transferred to an authorised site within the EU27/EEA and will be made available for inspection;

[2] For biological products a type IB or type II variation has to be submitted (depending on the test methods transferred) and completed before the implementation.
[3] Transfer of all batch release testing must be completed by this date and medicinal products not tested in EU27/EEA site(s) cannot be placed on EU27/EEA market after this date. This should be the earliest date possible but in any case no later than 31st December 2019.

☐ We have taken necessary steps to prepare for transfer of the quality control testing and the timelines indicated above do not exceed the time needed to implement batch release testing in the EU27/EEA;

☐ We will record information on individual batches released under this exemption and, upon request, will provide it to EMA and/or the relevant EU27/EEA national competent authorities;

☐ Currently there is no batch control site in the EU27/EEA authorised for batch control testing activities subject to this request (as detailed in sections 2 and 3).

Date: …

On behalf of the marketing authorisation holder: _____

Signature and printed name of the authorised contact person