How to request a delay for transfer of UK batch control testing to the EU/EEA after 29 March 2019

As indicated in a communication from the European Commission (https://ec.europa.eu/health/sites/health/files/files/documents/brexit_batchtesting_medicinalproducts_en.pdf) based on provisions of Article 20(b) of Directive 2001/83/EC and Article 24(b) of Directive 2001/82/EC competent authorities may for a limited time after UK's withdrawal from the Union allow, in justified cases, batch release to continue to rely on quality control testing performed in the United Kingdom. The conditions for accepting such requests are set out in this European Commission communication.

For nationally authorised medicinal products such requests should be submitted to the Reference Member State (RMS) (also copying CMSs) for MRP/DCP and to National competent authorities for products authorised through national procedure. All requests should be based on the annexed template and submitted as early as possible, but no later than on 29 March 2019, via e-mail or Eudralink to the national contact point of the relevant national competent authority (NCA). A list of national contact points is available on the CMDh website (http://www.hma.eu/535.html). The heading of the email is recommended as "Brexit batch control testing exemption <MRP/DCP number> *in case of MRP/DCP product or* <national MA number> *in case of products authorised via national procedure*". For medicinal products authorised via national procedure in Italy or in case of MRP/DCP product having Italy as RMS, a paper copy of the exemption request, originally signed, should be addressed to AIFA, Medicinal Products Authorization Department (*Area Autorizzazioni Medicinali*). In order to facilitate a prompt assessment of the request, a scanned signed version and an editable version of the request must be provided.

NCA/RMS will review the request and will inform at the earliest opportunity the marketing authorisation holder whether the exemption has been agreed. If the exemption is granted, the marketing authorisation holder must provide a copy of such exemption to the EU27/EEA competent authority that granted the manufacturing authorisation for the batch release site and to the qualified person of the batch release site. For batch release sites located in Italy, copy of granted exemption should be addressed to the following e-mail: brexit-italianrelease@aifa.gov.it.

Based on the exemption and batch control testing results from the site located in the UK, the qualified person can release batches specified in the exemption for placing on the Union market. By the end of agreed exemption period the new batch control testing site(s) in EU27/EEA have to be introduced and the batch control testing site(s) in the UK removed (changes subject to a type IA variation can be notified to the relevant NCAs within 2 months after the end of an agreed exemption).

Batches of authorised medicinal products that had already been placed on the EU27/EEA market before UK's withdrawal from the Union can remain on market. However, in the absence of an exemption as described above, authorised medicinal products that have only undergone batch control testing in the UK and not in EU27/EEA, cannot be placed on the EU27/EEA market after UK's withdrawal from the Union.

Marketing authorisation holders are reminded that such exemptions are limited to batch control testing and cannot be granted for location of batch release sites, qualified person for pharmacovigilance, pharmacovigilance master file or marketing authorisation holder.