



**Medicines & Healthcare products
Regulatory Agency**

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24/09/2019

Dear Head of Regulatory Affairs

Continued preparations in the event of a no-deal Brexit:

We wrote to you on 2 January 2019, about preparations for medicinal products that are the subject of a Community Marketing Authorisation. Our records indicate we have not received a reply. As we continue to prepare for Brexit, we are seeking the following information.

To facilitate the preparation for grandfathering of these authorisations to UK marketing authorisations, the Medicines and Healthcare Regulatory Agency (MHRA) has assigned a Product Licence (PL) number to these Centrally Authorised Products (CAPs) based on the existing UK practice for national licences.

To ensure that the preparation for grandfathering runs smoothly please refer to below:

- Check the list sent to you of your currently authorised CAPs and advise us as soon as possible of any errors or omissions in that list
- Review the list of assigned UK PL numbers and contact us as soon as possible if you have a query
- Advise us of any CAPs that you do not want to be converted into UK Market Authorisations (MA)
- Advise us of the UK marketing status of each of the products, i.e. marketed or not marketed
- Advise us of any of the product/presentation that has been withdrawn or cancelled
- Advise us if the Market Authorisation Holder (MAH) company number assigned to the list of products is incorrect
- Provide us with a single point of contact for all your products. (In the case of a company group, we need a contact for each MAH affiliate within that group)

Please advise us in writing at capconversion@mhra.gov.uk .

MAHs can opt-out of the grandfathering process for all or some of their CAPs by notifying the MHRA in writing by 21 November 2019. If an MAH chooses to opt-out, after 21 November 2019 their product(s) will no longer be licensed in the UK. This will mean they can no longer be placed on the market in the UK.

If you have received a new EU product licence or a new presentation to an existing product since 29 March 2019:

- Advise us of the product name for each presentation.
- Advise us of any CAPs that you do not want to be converted into UK MAs.
- Advise us of the MAH company number.
- Confirm with us the single point of contact for all your products. (In the case of a company group, we need a contact for each MAH affiliate within that group.)

Please advise us in writing at capconversion@mhra.gov.uk

The new or additional PL numbers will be sent to you prior to 31 October 2019.

In flight applications in the Centralised procedure

The MHRA has published a range of guidance to explain how it will handle the regulation of medicines and medical devices in the event of a no deal outcome. This guidance will apply from exit day when the Human Medicines Regulations (Amendment etc.) (EU Exit) Regulations 2019 come into force.

Specific guidance had been published on how the MHRA will handle centralised applications that are still pending on exit day, in the event of a no deal Brexit.

The approach of the MHRA is to take into account any assessment that has already been reported on by CHMP before exit day. The handling will be determined by the stage of the procedure the application will be on that day. As advised in that guidance the MHRA will assign an application manager to each application to guide you through the actions you need to take and avoid delays to the completion of the procedure.

If you have a pending application we intend to arrange a telephone call with you to start this process. We will prioritise applications that are at the later stages of the assessment process, so please reply to us as soon as possible with the name and contact details of the company representative with whom we should make arrangements.

The MHRA website has information concerning preparation for a no deal Brexit:

<https://www.gov.uk/government/collections/mhra-guidance-and-publications-on-a-possible-no-deal-scenario#marketing-authorisations,-variations-and-licensing-guidance>

In the meantime, if you have any questions about this conversion process, please send them to capconversion@mhra.gov.uk.

MHRA CAP Conversion Team