Medicines & Healthcare products Regulatory Agency

MHRA

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10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

+44 (0) 20 3080 6000

gov.uk/mhra

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Dear Head of Regulatory Affairs

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

Thank you for your reply to our letter of 2 January 2019. We are continuing to prepare for the UK exit from the EU and have logged your earlier response.

The purpose of this letter is to seek further information on any relevant changes that have occurred since 2 January, in particular for points 1 and 2 below.

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

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

1. 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 Market Authorisation Holder (MAH) company number.
    - If possible, 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

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

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.

2. **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 the Committee for Medicinal Products for Human Use (CHMP) before exit day. The handling will be determined by the stage of the procedure the application was at 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 prioritising the applications that are at the later stages of the assessment process. 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