Medicines & Healthcare products Regulatory Agency

MHRA

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Dear Head of Regulatory Affairs

Continued preparations in the event of a no-deal Brexit: In flight applications in the Centralised procedure

The Medicines and Healthcare products Regulatory Agency (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 has been published on how the MHRA will handle centralised applications that are still pending on exit day, in 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.

As 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 assessment. Please reply to us as soon as possible with the name and contact details of the company representative with whom we should make arrangements to capconversion@mhra.gov.uk.

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