From: Engagement <Engagement@mhra.gov.uk>
Sent: 06 March 2019 10:04
Subject: MHRA update on EU Exit incl. recently published guidance

Dear colleague

This is our regular update on recently published guidance that is intended to be enacted in the event of a no-deal EU exit, and other information which we hope you will find useful. Please share this email with your members.

Update on progress of legislation to allow the continued sale of, and access to, medicines, medical devices and clinical trials

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 and The Human Medicines (Amendment) Regulations 2019 are expected to be debated in the House of Commons today.

The Medicines for Human Use (Clinical Trials) (amendment) (EU exit) Regulations 2019, The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 and The Human Medicines (Amendment) Regulations 2019 are expected to be debated in the House of Lords on Thursday 7th March.

It is anticipated that these three Statutory Instruments will be approved by both Houses so that they can be made (signed into law) and brought into effect as law.

Guidance on operational changes

Leaving the EU with a deal remains the Government's top priority. This has not changed. However, a responsible government must plan for every eventuality, including a no-deal scenario. We are continuing with our no-deal planning to ensure we are fully prepared.

As you know, to support your preparations for a no-deal EU exit we are publishing guidance on operational changes on GOV.UK – as per the long list circulated a fortnight ago.

Recently published guidance:

- Regulating medical devices in the event of a no deal scenario
- Making submissions to the MHRA in a no deal scenario

Regarding pieces of guidance that are still to be published, we are doing everything possible to publish in line with target dates, but please do bear with us if/where a slight extension is required – as has been the case for some of the pieces due for publication last week. We will let you know as soon as these are published.

For any questions about the guidance, companies should please contact their trade body representatives who can check if a question has already been asked. Thereafter please can they contact the MHRA policy team, addressing the email to Natasha Craig and Sarah Harvey-Kelly, copying Ian King and Patrick Carey (all addresses are firstname.surname@mhra.gov.uk).

No-deal systems contingency programme update

We have produced a webinar explaining how to gain access to the MHRA submissions portal to make submissions to the MHRA if the UK leaves the EU with no deal. You can view the webinar here.

This webinar is relevant for:

- all pharmaceutical companies involved in making medicines regulatory submissions and vigilance activities
- all clinical trial sponsors wishing to submit clinical trial applications to the Agency
- e-cigarette producers
- brokers of medicinal products

The content covers the steps involved in gaining access to the portal, the critical role of the initial company administrator and guidance on how to manage access to third party consultants/consultancies who submit on a company's behalf.

To ensure that companies can make submissions to the MHRA from Day 1 in a no-deal scenario, companies can begin the process for gaining access to MHRA Submissions from today.

A further webinar relating to submitting vigilance information to the MHRA from Day 1 in a no-deal scenario was hosted on Friday 1st March. This webinar will be published this week and the ability to register for the relevant pharmacovigilance solution, either MHRA Gateway for Individual Case Safety Report (ICSR) submissions, will follow shortly.

We welcome your feedback on what other information you would find useful – please email engagement@mhra.gov.uk

Kind regards

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