[Note – Email attachment attached to our OLS update email]

From: Engagement <Engagement@mhra.gov.uk>
Sent: 14 March 2019 10:35
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 were debated and passed by a committee in the House of Commons last week.

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.

To support your preparations for a no-deal EU exit we are publishing guidance on operational changes on GOV.UK.

Recently published guidance:

- Importing medicines from an EEA State which is on an approved country for import list
- List of approved countries for authorised human medicines in a no deal scenario
- Guidance on importation of investigational medicinal products from approval countries
- Exporting active substance manufacturer in the UK if we leave the EU without a deal
- Guidance on air freight of medicines in a no deal scenario
- Guidance on qualified person responsible for pharmacovigilance (QPPV) including pharmacovigilance system master files (PSMF) if the UK leaves the EU without a deal
- Completed Paediatric Studies - submission, processing and assessment in the event of a no deal scenario
- Information for customers of biological reference materials regarding a no deal scenario
- Statement from NIBSC on science and research

No deal systems contingency programme update

We have produced a webinar explaining how to gain access to the MHRA Gateway or ICSR Submissions. You can view the webinar here.

This webinar is relevant for:

- all pharmaceutical companies responsible for submitting Individual Case Study Reports (ICSRs)
- all medicines clinical trial sponsors responsible for submitting Suspected Unexpected Serious Adverse Reactions (SUSARs)

The webinar content covers the steps involved in registering and setting up access to the MHRA Gateway. It also covers how to register for the ICSR Submissions solution for companies who will not be using the MHRA Gateway option.

In addition to the webinar we have published two user guidance documents and short video demonstrations of the new systems.

Companies submitting ICSRs and/or SUSARs through the MHRA Gateway will first need to gain access to the MHRA Submissions portal via a company administrator. To ensure that companies can make submissions to the MHRA from Day 1 in a no-deal scenario, companies can now begin the process for gaining access to MHRA Submissions.

For those who will need to submit vigilance information to the MHRA you can now begin the registration process for the MHRA Gateway or ICSR Submissions.

No deal systems contingency planning: information specific to clinical trials

We have distributed the attached guidance pack to stakeholders involved in Clinical Trials to prepare for a no-deal scenario. An email was sent directly to commercial and non-commercial sponsors and applicants on Monday 11th March. This pack provides those impacted by potential changes with a step by step guide to submitting Clinical Trial submissions via the MHRA portal; and information on registering and submitting SUSARs.

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

Kind regards

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