From: Engagement <Engagement@mhra.gov.uk>
Sent: 22 March 2019 15:16
To: Engagement <Engagement@mhra.gov.uk>
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

Statutory Instrument *The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019* has now passed in the Lords enabling six dependent Statutory Instruments (including The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, The Human Medicines (Amendment) Regulations 2019 and The Medicines for Human Use (Clinical Trials) (amendment) (EU exit) Regulations 2019) to now be made (signed into law) by 25 March.

No deal systems contingency programme update

Earlier this week we sent you details of the webinar we are hosting on Monday 25 March (10.30am to 12pm) on how to make a submission via MHRA Submissions. It will cover how to navigate around the MHRA Submissions homepage and the steps involved in sending a range of submission types through MHRA Submissions. It's relevant for:

- all pharmaceutical companies involved in making medicines regulatory submissions
- all medicines clinical trial sponsors wishing to submit clinical trial applications to the Agency

Please ask your members:

- to register to attend the webinar here: https://mhra.zoom.us/s/416704694
- when registering, use the 'last name' field to enter their organisation name.

We will also publish the webinar on GOV.UK as soon as possible after 25 March.

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.

To support your preparations for a no-deal EU exit we are publishing guidance on operational changes on GOV.UK and you can sign up to alerts here.

Recently published guidance:

Guidance on updates to packaging components and instructions on submissions if the UK leaves the EU without a deal for those marketing authorisations (MA) issued following conversion of EU MA

Procedures for UK-PIPs in the event the UK leaves the EU without a deal

Guidance on Marketing Authorisation Applications submitted to the UK that have been referred under Article 29 in a no deal scenario

Handling of Active Substance Master Files and Certificates of Suitability in the event of no deal

Guidance on Converting Parallel Distribution Notices (PDNs) to UK Parallel Import Licences (PILs) in a no deal scenario

Guidance on the handling of applications for Centrally Authorised Products (CAPs) pending on exit day

Guidance on handling of Decentralised and Mutual Recognition Procedures in a no deal scenario

Guidance note on new assessment routes in a no deal scenario

Guidance on Reference Medicinal Products (RMPs) if the UK leaves the EU without a deal

Guidance on how variations to Marketing Authorisations (MAs) will be handled after exit day if the is no deal

Converting Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs) in a no deal scenario, 'grandfathering' and managing lifecycle changes

Guidance on pharmacovigilance procedures in the event the UK leaves the EU without a deal

How renewals of Marketing Authorisations will be handled in a no deal scenario

How UK orphan medicinal products will be managed in a no deal scenario

Guidance on new provisions for traditional herbal medicinal products and homoeopathic medicinal products in a no deal scenario

Licensing of biological products, biosimilars, Advanced Therapy Medicinal Products (ATMPs) and Plasma Master Files (PMFs) in a no deal scenario

Guidance on registration of clinical trials for investigational medicinal products and publication of summary results

Additional guidance published as an updated, supplementary section to the Devices no deal guidance page

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