Press release: MHRA to consult on EU exit no-deal legislative proposals

The UK is exiting the EU on 29 March 2019. The UK and EU negotiating teams have reached agreement on the terms of an Implementation Period that will start on 30 March 2019 and last until 31 December 2020. With talks ongoing, we remain committed to reaching agreement on the Withdrawal Agreement and Future Framework in the Autumn.

However, a responsible government should prepare for all potential outcomes, including the unlikely scenario in which no mutually satisfactory agreement can be reached and that is exactly what we are doing, with this consultation forming part of these preparations.

As part of this contingency planning it is necessary to make sure the UK's regulatory processes for medicines, clinical trials and medical devices are legally coherent on exit day.

This consultation covers changes to four different Statutory Instruments (SIs): the Medicines for Human Use (Clinical Trials) Regulations 2004, the Medical Devices Regulations 2002 and the Human Medicines Regulations 2012 (HMRs) and the Medicines (Products for Human Use) (Fees) Regulations 2016. The changes to the latter two instruments are combined in a single SI.

The overall approach in the unlikely event of a no-deal scenario is for the MHRA to be a stand-alone medicines and medical devices regulator, taking any decisions and carrying out any functions which are currently taken or carried out at EU-level.

Many of the changes to these SIs are of a technical nature which will remove relevant references to the EU, insert references to the UK and other similar changes. The legislation is still being drafted and we are not consulting on the exact legal texts. Rather, this consultation gives narrative on any amendments being considered, with the following principles having been applied:

- a pragmatic and proportionate approach in establishing UK regulatory requirements
- the UK regulator's ability to take regulatory action to protect public safety
- minimum disruption and burden on companies as the UK exits the EU

Dr Ian Hudson, Chief Executive Officer at the MHRA said:

> Our position on medicines and medical devices regulation remains clear. We want to retain a close working partnership with the EU to make sure patients continue to have timely access to safe medicines and medical devices. However, it is important for the UK to prepare for all scenarios and this consultation is a key part of that.

> I therefore strongly encourage anyone that has an interest to share their comments.
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> The MHRA's vision for the future of medicines and medical devices regulations is underpinned by three clear principles, that patients should not be disadvantaged, that innovators should be able to get products to the UK market as quickly and simply as possible, and that the UK continues to play a leading role promoting public health.
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> In the unlikely event of a no-deal scenario, the UK will strive to be at the forefront of regulatory innovation and processes. For example, looking at ways to reduce the length of time required to approve new medicines.

The consultation, available online, will close at 23:45 on 1 November 2018 and its outcomes will be communicated.

Ends

Notes to Editor

1. Statutory Instruments (SIs) are a form of legislation which allow the provisions of an Act of Parliament to be subsequently brought into force or altered without Parliament having to pass a new Act.

2. Further information about the UK government's preparations for a no deal scenario can be found here.