Press release: MHRA releases response to consultation on EU exit no-deal legislative proposals

The UK is leaving the EU on 29 March 2019. We remain focused on delivering the deal that we have negotiated with the EU. However, as a responsible government, it is right that we continue to prepare for all scenarios and provide information so that other organisations can do the same.

Following our consultation on how medicines, medical devices and clinical trials would be regulated in a no-deal scenario, we have today issued updated guidance setting out the UK's proposed arrangements for regulation if we leave the EU on 29 March 2019 with no deal.

For medicines, the key arrangements include:

- automatically converting Centrally Authorised Products (CAPs) to UK Marketing Authorisations (MAs), a process known as 'grandfathering'
- targeted assessment of new applications for products containing new active substances or biosimilars which have been submitted to the EMA and received a Committee for Medicinal Products for Human Use (CHMP) positive opinion
- a full accelerated assessment for new active substances
- free scientific advice, including for orphan medicines, for UK-based small and medium-sized enterprises (SMEs)
- a period until the end of 2021 to amend packaging and leaflets for a product already on the market
- allowing the parallel import of medicinal products that hold a marketing authorisation from an EU or EEA country
- continuing to recognise prescriptions issued in EU or EEA countries.

For medical devices, the key arrangements include:

- for a time-limited period, devices that have a CE mark from a notified body based in the UK or an EU country will continue to be recognised by

UK law and allowed to be placed on the UK market

- the expansion of the MHRA's registration system to all classes of medical device.

For clinical trials, the key arrangements include:

- continuing to recognise existing approvals so there will be no need to re-apply

- requiring the sponsor or legal representative of a clinical trial to be in the UK or country on an approved country list which would initially include EU or EEA countries

- aligning, where possible, with the EU Clinical Trials Regulation when it applies.

Further detailed guidance is available in the Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal.

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

> 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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> The responses to our consultation have helped us prepare a robust plan to make sure our regulatory processes for medicines, clinical trials and medical devices are fit for purpose on exit day.
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> We are committed to giving businesses and individuals as much certainty as possible, as soon as possible to make sure the UK continues to be at the forefront of regulatory innovation and processes.

These proposals are still subject to parliamentary approval of the relevant statutory instruments that are required to bring these proposals into law.

Ends

Notes to Editor

1.The MHRA is responsible for regulating all medicines and medical devices in the UK. All our work is underpinned by robust and fact-based judgments to ensure that the benefits justify any risks. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The Agency is an executive agency of the Department of Health and Social Care. www.mhra.gov.uk 2.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. 3.Further information about the UK government's preparations for a no deal scenario can be found here.