Contingency legislation covering regulation of medicines and medical devices in a no deal scenario

Legislation has been published which, in the event of the UK leaving the EU with no agreement, will cover the regulation of medicines, medical devices and clinical trials.

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From:

Medicines and Healthcare products Regulatory Agency

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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.

Contingency legislation is needed in order for the Medicines and Healthcare products Regulatory Agency (MHRA) to be able to take on regulatory processes for human medicines and devices that are currently undertaken by the European Medicines Agency and other bodies.

The three separate pieces of legislation will allow for the continued sale of, and access to, medicines, medical devices and clinical trials:

1. Human Medicines Regulations 2012, as amended by the Human Medicines (Amendment etc) (EU Exit) Regulations 2019
2. The Medical Devices (amendment) (EU exit) Regulations 2019
3. The Medicines for Human Use (Clinical Trials) (amendment) (EU exit) Regulations 2019

These Regulations have been approved by Parliament and were made in April 2019.

The Human Medicines and Medical Devices (Amendment etc.) (EU exit) Regulations 2019 have been laid in parliament today (24 July 2019).

This instrument makes a number of changes to the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 and the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 to ensure that the UK legislation accurately reflects technical updates at EU level since April 2019 and also corrects drafting errors and omissions to reflect published policy in the event of a no deal Brexit.

Full details of the changes are set out in the explanatory memorandum.

The legislation will be subject to parliamentary scrutiny and approval which we anticipate in the autumn.

Background

These Regulations set out a comprehensive regime for the authorisation of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance.

They also provide for enforcement powers for the authorisation and supervision of medicinal products for human use.

The 2012 Regulations (as amended by the 2019 Regulations) make reference to various pieces of EU guidance, as that stood immediately before exit day (29 March 2019).

The Agency is the designated competent authority that administers and enforces the law on medical devices in the UK. It has a range of investigatory and enforcement powers to ensure their safety and quality. These regulations ensure that the required powers are provided for.

The Clinical Trial Regulations require all interventional clinical trials of medicines to be authorised by the MHRA, as the national competent authority in the UK; to have a favourable ethics opinion; and to be conducted according to Good Clinical Practice. They also include requirements for the assessment and supply of investigational medicinal products and for safety reporting.