Commons Research Briefing Medicine Sciences

Medicines and Medical Devices Bill 2019-21

Published Friday, June 19, 2020 Bukky Balogun, Elizabeth Rough

The Medicines and Medical Devices Bill 2019-21 (Bill 136) was introduced in the Commons on 13 February 2020 and had its Second Reading on 2 March 2020. The Committee Stage ran from 8-10 June 2020 and remaining Commons stages are scheduled for 23 June 2020.

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Context for the Bill

A large proportion of the legal framework for medicines and medical devices in the UK derives from EU Directives and has been implemented into domestic legislation through section 2(2) of the *European Communities Act 1972* (ECA). This enables EU Directives to be transposed into UK law through secondary legislation and has been used to create a body of regulations that include the:

- Human Medicines Regulations 2012
- Medicines for Human Use (Clinical Trials) Regulations 2004
- Veterinary Medicines Regulations 2013
- Medical Devices Regulations 2002.

The ECA, however, will no longer be available to the UK at this point to amend the regulations. There is no other 'general power' for updating these regulations, except through the introduction of primary legislation.

What does the Bill do?

The Medicines and Medical Devices Bill seeks to address this regulatory gap through introducing regulation-making, delegated powers covering the fields of human medicines, clinical trials of human medicines, veterinary medicines and medical devices. Its purpose is to enable the existing regulatory frameworks to be updated at the end of the Transition Period. The Bill has been drawn to create 'targeted' delegated powers which can only be exercised in relation to a restricted number of matters. The Government stated in the Explanatory Notes to the Bill that it intends to use these powers to keep the existing regulatory frameworks updated, while also consolidating the enforcement regime for medical devices. In addition, the Bill will provide the Secretary of State with the ability to impose civil sanctions – as an alternative to criminal prosecution – for breaches of the medical device regime.

The Government has indicated in the background briefing to the Queen's Speech and in a press release that they intend to use these powers to support the development of medicines and medical devices within the NHS and amend prescribing powers.

Part 1 of the Bill creates a delegated power to amend or supplement human medicines law. The power is restricted to amending four pieces of legislation: the *Human Medicines Regulations 2012*, the *Medicines for Human Use (Clinical Trials) Regulations 2004*, the *Medicines (Products for Human Use) Regulations 2016* and limited parts of the *Medicines Act 1968* (specifically those parts which make provision related to pharmacies). It is then further restricted to amending or updating only those provisions stated on the face of the Bill. These are:

- the manufacture, marketing and supply of human medicines;
- falsified medicines;
- clinical trials;
- the charging of fees in relation human medicines provision;
- creating an offence for failing to comply with human medicine regulations;

Part 2 of the Bill confers a delegated power to amend or supplement the *Veterinary Medicines Regulations 2013* and specifically those regulations that relate to:

- the manufacture, marketing, supply and field trials of veterinary medicines;
- the charging of fees in relation human medicines provision;
- creating an offence for failing to comply with veterinary medicine regulations;
- the powers of a Veterinary Medicines Directorate Inspector.

Part 3 of the Bill creates a delegated power to enable the *Medical Devices Regulations (MDR) 2002* to be updated, though the Bill stipulates that the Regulations may only be amended in relation to a limited number of areas, namely:

- the manufacture, marketing and supply of medical devices;
- the charging of fees in relation to medical devices (eg to register a device);
- recording information about the safety of devices;
- creating offences of breaching the provisions in the MDR; and
- the supply of medical devices in emergencies.

Part 3 of the Bill also aims to consolidate the enforcement regime for ensuring the safety and quality of medical devices. It provides the Secretary of State with new information sharing powers relating to the safety of a medical device.

Part 4 of the Bill creates a duty to consult before any changes to regulations are made under Clauses 1(1), 8(1) and 12(1) and also provides that the statutory instruments made under these clauses will be subject to the affirmative resolution procedure. Exceptions to the duty to consult, and to the use of the affirmative procedure, are outlined in the paper.

How does the Bill apply to UK nations?

The Bill extends to England, Northern Ireland, Scotland and Wales. Parts 1 and 2 of the Bill (relating to Human Medicines and Veterinary Medicines respectively) are within the legislative competence of the Northern Ireland Assembly and a legislative consent motion has been sought for those parts.

The Committee Stage ran from 8-10 June 2020. Technical amendments were moved by the Government and agreed. No other amendments were made. The Government promised to discuss a UK registry for medical devices, outside of the Committee, following a proposed new clause on this matter.

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