



House of Commons

NOTICES OF AMENDMENTS

given up to and including

Wednesday 4 March 2020

New Amendments handed in are marked thus ★

☆ *Amendments which will comply with the required notice period at their next appearance*

Amendments tabled since the last publication: NC1

PUBLIC BILL COMMITTEE

MEDICINES AND MEDICAL DEVICES BILL

NOTE

This document includes all amendments tabled to date and includes any withdrawn amendments at the end. The amendments have been arranged in the order in which they relate to the Bill.

Anne Marie Morris

NC1

★ To move the following Clause—

“National Medical Devices Registry and governance

- (1) The Secretary of State must by regulations establish a national registry of medical devices the purpose of which shall be—
 - (a) to record—
 - (i) every medical device implanted in, or
 - (ii) inserted into a patient.
 - (b) to consolidate existing English registries and require their owners to migrate their data to such a registry, ensuring all GDPR consents have been obtained or deemed obtained and to organise such data in a common and consistent way.

Medicines and Medical Devices Bill, *continued*

- (2) In designing such a registry, the Secretary of State must take account of existing international—
- (a) frameworks;
 - (b) terminology;
 - (c) protocols; and
 - (d) quality standards
- to enable better international learning, collaboration, health outcomes, research and product improvement globally.
- (3) For the purposes of subsection (1), every device shall be required to have its own unique identifier. Manufacturers of such devices or components of such devices shall be required to provide the identification data of every device or device component to the registry on manufacture, and on its sale or change of ownership.
- (4) Clinical Commissioning Groups in England shall require all health service providers using medical devices covered by this section to put in place a system to require NHS trusts to record the clinical use of any such device or component of such devices on the registry when used in their population. The records must include—
- (a) the date of use,
 - (b) the nature of the procedure,
 - (c) the clinicians performing the procedure
 - (d) clinical information about the condition of the patient at the point of use and thereafter on any future reviews of the performance of the device, and
 - (e) health outcomes, including their prospective collection.
- (5) Every health service provider whose clinicians are implanting or inserting medical devices shall establish its own procedure and protocols to record the data as prescribed in this Act and by the Secretary of State in regulations made under this Act, which shall be consistent, efficient and integrated into the health care pathway for the medical procedure in question.
- (6) The Secretary of State shall by regulation establish a stakeholder consultation group with which to consult on the governance of any registry established under subsection (1). The stakeholder group which must include—
- (a) patients and patient groups,
 - (b) current national and international medical device registries,
 - (c) the Royal College of Surgeons, the Royal College of Physicians,
 - (d) the Nursing and Midwifery Council,
 - (e) the Medicines and Healthcare Products Regulatory Agency,
 - (f) the National Institute for Health and Care Excellence,
 - (g) NHS England and NHS Improvement,
 - (h) such other regulatory bodies as shall have a regulatory role,
 - (i) manufacturers, suppliers, commissioners, and health care providers and their representative bodies,
 - (j) academic experts in designing and analysing register data, and
 - (k) NHSX and NHS Digital.
- (7) The Secretary of State shall create such posts or bodies as needed to ensure the creation and maintenance of the registry, and to ensure it delivers on its objectives.

Medicines and Medical Devices Bill, *continued*

- (8) The Secretary of State shall establish by regulations a mechanism ensuring that the registry is accountable and delivers on its objectives, and to enable transparency and access to the data in the registry by health care providers and Clinical Commissioning Groups and such other national and international bodies as the Secretary of State shall authorise.

ORDER OF THE HOUSE [2 MARCH 2020]

That the following provisions shall apply to the Medicines and Medical Devices Bill:

Committal

1. The Bill shall be committed to a Public Bill Committee.

Proceedings in Public Bill Committee

2. Proceedings in the Public Bill Committee shall (so far as not previously concluded) be brought to a conclusion on Thursday 23 April 2020.
3. The Public Bill Committee shall have leave to sit twice on the first day on which it meets.
4. Proceedings on Consideration and any proceedings in legislative grand committee shall (so far as not previously concluded) be brought to a conclusion one hour before the moment of interruption on the day on which proceedings on Consideration are commenced.
5. Proceedings on Third Reading shall (so far as not previously concluded) be brought to a conclusion at the moment of interruption on that day.
6. Standing Order No. 83B (Programming committees) shall not apply to proceedings on Consideration and up to and including Third Reading.

Other proceedings

7. Any other proceedings on the Bill may be programmed.
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