House of Commons

Wednesday 10 June 2020

PUBLIC BILL COMMITTEE PROCEEDINGS

MEDICINES AND MEDICAL DEVICES BILL

[THIRD AND FOURTH SITTINGS]

GLOSSARY

This document shows the fate of each clause, schedule, amendment and new clause.

The following terms are used:

Agreed to: agreed without a vote.
Agreed to on division: agreed following a vote.
Negatived: rejected without a vote.
Negatived on division: rejected following a vote.
Not called: debated in a group of amendments, but not put to a decision.
Not moved: not debated or put to a decision.
Question proposed: debate underway but not concluded.
Withdrawn after debate: moved and debated but then withdrawn, so not put to a decision.
Not selected: not chosen for debate by the Chair.

Alex Norris

Withdrawn after debate **29**

Clause **17**, page **10**, line **12**, at end insert—
"(f) advertising it."

Alex Norris

Withdrawn after debate **18**

Clause **18**, page **10**, line **34**, at end insert—
"(f) advertising it."

Medicines and Medical Devices Bill, *continued*

Clauses 18 to 23 agreed to.

Jo Churchill
Dr Philippa Whitford

Agreed to **2**

Clause **24**, page **13**, line **26**, leave out "case" and insert "proceedings for such an offence"

Jo Churchill
Dr Philippa Whitford

Agreed to **3**

Clause **24**, page **13**, line **32**, after "hearing" insert "of the proceedings"

Jo Churchill
Dr Philippa Whitford

Agreed to **4**

Clause **24**, page **14**, line **2**, at the end insert ", and

(b) the reference in subsection (3) to "the hearing of the proceedings" is to be read as a reference to "the trial diet"."

Clause, as amended, agreed to.

Clauses 25 and 26 agreed to.

Alex Norris
Dr Philippa Whitford

Withdrawn after debate **20**

Schedule **1**, page **31**, line **16**, after "guidance" insert "within three months of this Act receiving Royal Assent"

Alex Norris
Dr Philippa Whitford

Withdrawn after debate **21**

Schedule **1**, page **32**, line **18**, leave out "from time to time" and insert "every 12 months"

Schedule 1 agreed to.

Clauses 27 and 29 agreed to.

Medicines and Medical Devices Bill, *continued*

Alex Norris
Dr Philippa Whitford

Withdrawn after debate **28**

Clause **30**, page **16**, line **23**, at end insert—

"(4) The Secretary of State must, within 24 months of this Act receiving Royal Assent, lay a report before Parliament reviewing uses of this clause."

Clauses 31 and 36 agreed to.

Jo Churchill
Dr Philippa Whitford

Agreed to **5**

Schedule **2**, page **34**, line **8**, leave out "case" and insert " proceedings for such an offence"

Jo Churchill
Dr Philippa Whitford

Agreed to **6**

Schedule **2**, page **34**, line **14**, after "hearing" insert "of the proceedings"

Jo Churchill
Dr Philippa Whitford

Agreed to **7**

Schedule **2**, page **34**, line **28**, at the end insert "and

(b) the reference in paragraph (3) to "the hearing of the proceedings" is to be read as a reference to "the trial diet"."

Schedules 2, as amended, agreed to.

Clauses 37 and 42 agreed to.

Alex Norris
Dr Philippa Whitford

Withdrawn after debate **19**

Clause **43**, page **24**, line **17**, leave out "on such day or days as the Secretary of State may by regulations made by statutory instrument appoint" and insert "six months after this Act receives Royal Assent."

Clauses 44 and 45 agreed to.

Medicines and Medical Devices Bill, *continued*

Anne Marie Morris

Not selected **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.

(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, and information on how such records will be collected in future.

(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,

Medicines and Medical Devices Bill, *continued*

(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.

(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.

Alex Norris

Not called **NC2**

To move the following Clause—

"Report on medicines under development

On the date on which this Act is passed, and once every twelve months thereafter, the Secretary of State must lay before Parliament a report detailing what medicines the UK Government are developing."

Alex Norris

Not called **NC3**

To move the following Clause—

"Report on availability of medicines

The Secretary of State must report to Parliament when a medicine which is clinically beneficial has not been made available on the NHS."

Medicines and Medical Devices Bill, *continued*

Alex Norris
Dr Philippa Whitford

Not called **NC4**

To move the following Clause—

"Antimicrobial Resistance

(1) The Secretary of State must regard antimicrobial resistance a priority in the development of new medicines.

(2) The Secretary of State must, within 12 months of this Act receiving Royal Assent, lay an updated report before Parliament setting out a UK-wide strategy for tackling antimicrobial resistance."

Alex Norris

Not called **NC5**

To move the following Clause—

"Capacity of the veterinary industry

(1) The Secretary of State must, within 12 months of making regulations under section 8(1), lay a report before Parliament setting out an assessment of the capacity of the veterinary industry, relative to the requirements of those regulations."

Dr Philippa Whitford
Alex Norris
Anne Marie Morris

Withdrawn after debate **NC6**

To move the following Clause—

"Registration of Medical Devices

(1) The Secretary of State shall by regulations establish a UK Registry of all devices implanted into patients on a long-term basis.

(2) The identifier details of any devices implanted into patients, on a long-term or permanent basis, must be registered.

(3) The information registered must include—

(a) The unique identifier of the patient into whom the device is implanted;

(b) The Clinician responsible for the procedure;

(c) The hospital or clinic in which the procedure is performed;

(d) A standardised description of the device;

(e) The unique identifier code of the device implanted.

(4) Efforts must be made for this unique identifier data to be gathered by barcode reader as in the trial of 'Scan for Safety'.

(5) This Registry shall require linkage from all currently established speciality device registries, in current operation, to avoid duplication of registration.

(6) Devices without any form of specialist registry currently available shall be registered in this UK Registry.

Medicines and Medical Devices Bill, *continued*

(7) Governance structures regarding the management and access to registry data shall be established after consultation with stakeholders including but not limited to—

(a) the appropriate authorities as defined in Section 1 (4);

(b) all UK based Royal Colleges of Surgery or Radiology and any others representing clinicians involved in such procedures;

(c) Managers of current speciality device registries;

(d) the Medicines and Healthcare products Regulatory Agency;

(e) the Directors of each of the four UK based National Health Services;

(f) healthcare quality improvement bodies from each of the four UK based National Health Services;

(g) representatives of the Healthcare device manufacturing sector;

(h) academics with expertise in the design and maintenance of registries;

(i) additional stakeholders as identified during the development and maintenance of such a registry.

(8) Patient information from such a registry shall be provided to clinicians if there is concern regarding the management of or complications from any implanted device to allow closer monitoring or removal if so warranted."

Dr Philippa Whitford
Alex Norris

Not selected **NC7**

To move the following Clause—

"Requirement for consolidated legislation

The Secretary of State is required to introduce to Parliament new primary legislation consolidating the existing regulatory regime as it applies to Medical Devices by the date 2 years following Royal Assent."

Dr Philippa Whitford
Alex Norris

Not selected **NC8**

To move the following Clause—

"Time limits on delegated powers

Sections 1, 8 and 12 of this Act, and the powers they confer therein, shall be revoked on the date that is 2 years after their implementation."

Bill, as amended, to be reported.