



House of Commons

Wednesday 10 June 2020

PUBLIC BILL COMMITTEE PROCEEDINGS

MEDICINES AND MEDICAL DEVICES BILL

[FIRST TO 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Withdrawn after debate: moved and debated but then withdrawn, so not put to a decision.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.

FIRST AND SECOND SITTINGS

Jo Churchill

Agreed to

That—

- (1) the Committee shall (in addition to its first meeting at 11.30 am on Monday 8 June) meet—
 - (a) at 3.30 pm on Monday 8 June;
 - (b) at 9.25 am and 2.00 pm on Wednesday 10 June;
- (2) the proceedings shall be taken in the order shown in the first column of the following Table;
- (3) the proceedings shall (so far as not previously concluded) be brought to a conclusion at the times specified in the second column of the Table.

Medicines and Medical Devices Bill, *continued*
TABLE

<i>Proceedings</i>	<i>Time for conclusion of proceedings</i>
Clauses 1 to 4	1 pm on Monday 8 June
Clauses 5 to 11	6 pm on Monday 8 June
Clauses 12 to 26; Schedule 1; Clauses 27 to 33	11.25 am on Wednesday 10 June
Clauses 34 to 36; Schedule 2; Clauses 37 to 45; new Clauses; new Schedules; remaining proceedings on the Bill	5 pm on Wednesday 10 June

Jo Churchill

That, subject to the discretion of the Chair, any written evidence received by the Committee shall be reported to the House for publication.

Agreed to

Jo Churchill

That, at this and any subsequent meeting at which oral evidence is to be heard, the Committee shall sit in private until the witnesses are admitted.

Not moved

Alex Norris

Clause 1, page 1, line 5, at end insert “for a period of two years following Royal Assent.” *Withdrawn 9*

Alex Norris
Dr Philippa Whitford

Clause 1, page 1, leave out lines 10 to 16 *Withdrawn 22*

Alex Norris
Dr Philippa Whitford

Clause 1, page 2, line 3, at end insert— *Not called 23*
“(5) In making regulations under subsection (1), the appropriate authority must give primary regard to the safety of human medicines.”

Medicines and Medical Devices Bill, continued

Clause 1 agreed to.

Ms Marie Rimmer
Dr Philippa Whitford

Negatived on division 1

Clause 2, page 2, line 23, at end, insert—

“(o) the origin and treatment of human organs used in the process of 2
developing or manufacturing medicines”

Clauses 2 and 3 agreed to.

Alex Norris
Dr Philippa Whitford

Not called 8

Clause 4, page 3, line 25, at end insert—

“(f) to support the involvement of the UK in EU-wide clinical trials.”

Alex Norris

Not called 10

Clause 4, page 3, line 25, at end insert—

“(1A) The Secretary of State must lay before Parliament a report outlining which
proposed clinical trials related to human medicines have been rejected in the
preceding 3 months.

(1B) The first report mentioned in subsection (1A) must be laid before Parliament
within three months of this Act coming into force, with subsequent reports laid
every three months thereafter.”

Clause 4 agreed to.

Alex Norris

Withdrawn 11

Clause 5, page 3, line 39, at end insert—

“(1A) The Secretary of State must publish a fees regime within three months of the date
on which this Act receives Royal Assent.”

Clauses 5 to 7 agreed to.

Alex Norris

Withdrawn 12

Clause 8, page 5, line 17, at end insert “services.”

Medicines and Medical Devices Bill, *continued*

Alex Norris
Dr Philippa Whitford

Clause 8, page 5, leave out lines 18 to 24

Not called 24

Alex Norris
Dr Philippa Whitford

Clause 8, page 5, line 32, at end insert—

“(5) In making regulations under subsection (1), the appropriate authority must give primary regard to the safety of veterinary medicines in relation to animals, humans and the environment.”

Not called 25

Clause 8 agreed to.

Alex Norris
Dr Philippa Whitford

Clause 9, page 6, line 11, at end insert—

“(1A) The Secretary of State must by regulations make provision about the use of the Cascade.”

Withdrawn 13

Clause 9 agreed to.

Alex Norris

Clause 10, page 6, line 35, at end insert—

“(1A) The Secretary of State must publish a fees regime within three months of the date on which this Act receives Royal Assent.”

Withdrawn 14

Clauses 10 and 11 agreed to.

Alex Norris
Dr Philippa Whitford

Clause 12, page 7, line 27, at end insert—

“(d) the environmental sustainability of medical devices.”

Withdrawn 15

Alex Norris
Dr Philippa Whitford

Clause 12, page 7, leave out lines 26 and 27

Not called 26

Medicines and Medical Devices Bill, *continued*

Alex Norris
Dr Philippa Whitford

Not called 27

Clause 12, page 7, line 27, at end insert—

“(3) In making regulations under subsection (1), the appropriate authority must give primary regard to the safety of medical devices.”

Clause 12 agreed to.

Alex Norris

Withdrawn 16

Clause 13, page 8, line 22, at end insert—

“(1A) In making regulations under section 12(1), the Secretary of State must evaluate the extent to which the market is meeting medical need.”

Alex Norris

Withdrawn 17

Clause 13, page 8, line 22, at end insert—

“(k) enabling the Secretary of State to compile a register of representatives for non-UK manufacturers.”

Clauses 13 to 16 agreed to.

THIRD AND FOURTH SITTINGS

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.”

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”

Medicines and Medical Devices Bill, continued

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.

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.

Medicines and Medical Devices Bill, *continued*

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.

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.

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, 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,
 - (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.

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.”

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.”
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Medicines and Medical Devices Bill, *continued*

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.
- (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.

Medicines and Medical Devices Bill, *continued*

- (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.
