House of Commons

Wednesday 10 June 2020

PUBLIC BILL COMMITTEE

New Amendments handed in are marked thus ★

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

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This document includes all amendments tabled to date and includes any withdrawn amendments at the end.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 accordance with the Order of the Committee [8 June 2020].

Alex Norris

29

Clause **17**, page **10**, line **12**, at end insert—

"(f) advertising it."

Member's explanatory statement

This amendment allows the enforcement authority to prevent an individual who has been served a suspension note from advertising their product.

Alex Norris

18

Clause **18**, page **10**, line **34**, at end insert—

"(f) advertising it."

Member's explanatory statement

This amendment allows the enforcement authority to prevent an individual who has been served a safety note from advertising their product.

Medicines and Medical Devices Bill, *continued*

Jo Churchill
Dr Philippa Whitford

2

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

Member's explanatory statement

This amendment, and amendments 3, 4, 5, 6 and 7, amend certain provisions to ensure they operate effectively in relation to Scotland.

Jo Churchill
Dr Philippa Whitford

3

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

Member's explanatory statement

See the explanatory statement for Amendment 2.

Jo Churchill
Dr Philippa Whitford

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"."

Member's explanatory statement

See the explanatory statement for Amendment 2.

Alex Norris
Dr Philippa Whitford

20

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

Member's explanatory statement

This amendment requires the relevant guidance relating to enforcement to be published within 3 months rather than at an undetermined time.

Alex Norris
Dr Philippa Whitford

21

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

Member's explanatory statement

This amendment requires the Secretary of State to report back on their use of civil sanctions every year rather than at an undetermined frequency

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Medicines and Medical Devices Bill, *continued*

Alex Norris
Dr Philippa Whitford

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."

Member's explanatory statement

This amendment requires the Government to review any use of the recall powers made in the first 2 years of the Act.

Jo Churchill
Dr Philippa Whitford

5

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

Member's explanatory statement

See the explanatory statement for Amendment 2.

Jo Churchill
Dr Philippa Whitford

6

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

Member's explanatory statement

See the explanatory statement for Amendment 2.

Jo Churchill
Dr Philippa Whitford

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"."

Member's explanatory statement

See the explanatory statement for Amendment 2.

Alex Norris
Dr Philippa Whitford

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."

Member's explanatory statement

This amendment brings the enforcement regime into force at a defined period after Royal Assent rather than at a date of the Government's choosing.

Medicines and Medical Devices Bill, *continued*

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.

(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.

Member's explanatory statement

This new clause requires the Government to create a national registry of implanted and inserted medical devices which tracks their history and the patient experience to improve patient safety, enable efficient recall if needed and to evaluate device performance.

Alex Norris

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."

Member's explanatory statement

This new clause requires the Secretary of State to lay before Parliament a report covering medicines that the UK Government are developing.

Medicines and Medical Devices Bill, *continued*

Alex Norris

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."

Member's explanatory statement

This new clause requires the Secretary of State to report to Parliament when a medicine which is effective has not been made available on the NHS.

Alex Norris
Dr Philippa Whitford

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."

Member's explanatory statement

This new clause requires the Government to prioritise tackling antimicrobial resistance and produce an updated report setting out how it shall do so.

Alex Norris

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."

Member's explanatory statement

This new clause requires the Government to make an assessment of the capacity of the veterinary industry.

Medicines and Medical Devices Bill, *continued*

Dr Philippa Whitford
Alex Norris
Anne Marie Morris

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.

(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."

Member's explanatory statement

The aim of such a UK register is to ensure earlier recognition of complications from implantable devices and allow the easy identification and urgent recall of affected patients should such a concern be recognised.

Medicines and Medical Devices Bill, *continued*

Dr Philippa Whitford
Alex Norris

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."

Member's explanatory statement

This new clause would commit the Secretary of State to introducing new, consolidated legislation within two years.

Dr Philippa Whitford
Alex Norris

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."

Member's explanatory statement

This new clause would ensure that the delegated powers are time limited to 2 years following Royal Assent for all delegated powers conferred by the Bill.

ORDER OF THE HOUSE [2 MARCH 2020, AS AMENDED 22 APRIL 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 11 June 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.

Medicines and Medical Devices Bill, *continued*

Other proceedings

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

ORDER OF THE COMMITTEE [8 JUNE 2020]

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.

TABLE

Proceedings	*Time for conclusion of proceedings*
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

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