House of Commons

NOTICES OF AMENDMENTS

given up to and including

Wednesday 3 June 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: 8 to 28, NC2 to NC5

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This document includes all amendments tabled to date and includes any withdrawn amendments at the end.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.

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.

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.

Medicines and Medical Devices Bill, *continued*

Alex Norris

9

★ Clause **1**, page **1**, line **5**, at end insert "for a period of two years following Royal Assent."

Member's explanatory statement

This amendment provides a sunset provision for the Bill requiring the Government to return with primary legislation.

Alex Norris

22

★ Clause **1**, page **1**, leave out lines 18 to 24

Member's explanatory statement

This amendment removes the requirement to consider the attractiveness of the relevant part of the UK when making regulations under subsection (1).

Alex Norris

23

★ Clause **1**, page **2**, line **3**, at end insert—

"(5) In making regulations under subsection (1), the appropriate authority must give primary regard to the safety of human medicines."

Member's explanatory statement

This amendment requires the appropriate authority to consider patient safety first when making regulations under subsection (1).

Ms Marie Rimmer

1

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

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

Member's explanatory statement

This amendment empowers the appropriate authority to make provisions on the process of developing or manufacturing medicines in relation to the origin and treatment of human organs.

Alex Norris

8

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

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

Member's explanatory statement

This amendment gives the Secretary of State powers to continue the UK's collaboration with clinical trials involving multiple EU countries.

Alex Norris

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.

Medicines and Medical Devices Bill, *continued*

(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."

Member's explanatory statement

This amendment would give the Secretary of State a duty to report rejected applications for proposed clinical trials related to human medicines.

Alex Norris

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."

Member's explanatory statement

This amendment requires the Secretary of State to publish their proposed list of fees in respect of human medicines.

Alex Norris

12

★ Clause **8**, page **5**, line **17**, at end insert "services."

Member's explanatory statement

This amendment broadens the range of issues that the Secretary of State must consider to include access to the relevant services to dispense veterinary medicines.

Alex Norris

24

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

Member's explanatory statement

This amendment removes the requirement to consider the attractiveness of the relevant part of the UK when making regulations under subsection (1).

Medicines and Medical Devices Bill, *continued*

Alex Norris

25

★ 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."

Member's explanatory statement

This amendment requires the appropriate authority to consider animal, human and environmental safety first when making regulations under subsection (1).

Alex Norris

13

★ 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."

Member's explanatory statement

This amendment gives the Secretary of State the responsibility to make provisions regarding the Cascade, a process where veterinarians can dispense different medicines to animals, such as human medicines, should appropriate conventional animal medicines not be available.

Alex Norris

14

★ 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."

Member's explanatory statement

This amendment requires the Secretary of State to publish their proposed list of fees in respect of veterinary medicines.

Alex Norris

15

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

"(d) the environmental sustainability of medical devices."

Member's explanatory statement

This amendment obliges the Secretary of State to pay regard to the environmental impact of medical devices.

Alex Norris

26

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

Member's explanatory statement

This amendment removes the requirement to consider the attractiveness of the relevant part of the UK when making regulations under subsection (1).

Medicines and Medical Devices Bill, *continued*

Alex Norris

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."

Member's explanatory statement

This amendment requires the appropriate authority to consider safety first when making regulations under subsection (1).

Alex Norris

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."

Member's explanatory statement

This amendment requires the Secretary of State to ensure that the market in devices is keeping pace with the UK's medical needs.

Alex Norris

17

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

"(l) enabling the Secretary of State to compile a register of representatives for non-UK manufacturers."

Member's explanatory statement

Manufacturers of medical devices based outside the UK must designate a UK representative. This gives the Secretary of State the power to compile a list of them.

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 suspension note from advertising their product.

Jo Churchill

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.

Medicines and Medical Devices Bill, *continued*

Jo Churchill

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

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

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.

Alex Norris

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.

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.

Medicines and Medical Devices Bill, *continued*

(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,

(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.

Medicines and Medical Devices Bill, *continued*

(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.

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.

Medicines and Medical Devices Bill, *continued*

Alex Norris

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.

Alex Norris

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

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*

Jo Churchill

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

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

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.

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.

Other proceedings

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