All line references relate to the large print version of the Bill

House of Commons

Tuesday 23 June 2020

CONSIDERATION OF BILL (REPORT STAGE)

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*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, AS AMENDED

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This document includes all amendments tabled to date and includes any withdrawn amendments at the end.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

All line references relate to the large print version of the Bill

Secretary Matt Hancock

NC1

To move the following Clause—

“Information systems

(1) The Secretary of State may by regulations make provision about the establishment and operation by the Health and Social Care Information Centre (“the Information Centre”) of one or more information systems for purposes relating to—

(a) the safety and performance, including the clinical effectiveness, of medical devices that are placed on the market;

(b) the safety of individuals who receive or are treated with a medical device, or into whom a medical device is implanted;

(c) the improvement of medical device safety and performance through advances in technology.

(2) The regulations may (among other things) make provision—

(a) specifying descriptions of information in relation to medical devices which may or must be entered or retained in an information system established under subsection (1);

(b) requiring information to be provided to the Information Centre for the purposes of its functions under the regulations;

(c) about the use or disclosure of information contained in an information system established under subsection (1);

(d) requiring the Information Centre to have regard to specified matters in exercising its functions under the regulations.

(3) The provision mentioned in subsection (2)(b) may include provision—

(a) requiring specified persons or descriptions of persons to whom subsection (4) applies to provide information of a specified description to the Information Centre;

(b) about the manner in which, and the time at which, those persons must provide that information;

(c) enabling the Information Centre to require specified persons or descriptions of persons to whom subsection (4) applies to provide to it in a manner, and at a time, determined by the Information Centre—

(i) information of a specified description;

(ii) information for specified purposes;

(iii) any other information that the Information Centre considers it necessary or expedient to have for the purposes of its functions under the regulations;

(d) about any procedural steps the Information Centre must follow in requiring a person to provide information to it;

(e) requiring specified persons or descriptions of persons to whom subsection (4) applies to record or retain information which they are, or

may be, required to provide to the Information Centre under the regulations;

(f) in relation to the enforcement of any requirement imposed by or under the regulations.

(4) This subsection applies to any person who provides services, or exercises any powers or duties, relating to medical devices.

(5) The descriptions of information specified in the provision mentioned in subsections (2)(a), (3)(a) and (3)(c)(i) may include—

(a) unique identifiers associated with medical devices;

(b) information in relation to individuals mentioned in subsection (1)(b);

(c) information about any procedure carried out in relation to a medical device (including information about any person involved in carrying out the procedure).

(6) The provision mentioned in subsection (2)(c) may include provision about—

(a) the analysis by the Information Centre of information contained in an information system (whether alone or in combination with other information) for the purposes mentioned in subsection (1) or for other purposes;

(b) the publication by the Information Centre of information contained in an information system;

(c) the disclosure (other than by way of publication) of information contained in an information system to specified persons or descriptions of persons, or for specified purposes;

(d) the use or further disclosure by any person of information disclosed to them under the regulations.

(7) The provision mentioned in subsection (3)(f) may include provision applying any provision of Chapter 2 of this Part (enforcement), with or

without modifications, in relation to a requirement imposed by or under the regulations.

(8) In this section, "specified" means specified in regulations under subsection (1)."

Member's explanatory statement

This new clause would give the Secretary of State power to make regulations providing for a database of information in relation to medical devices to be established and managed by the Health and Social Care Information Centre. The clause would be inserted after Clause 15.

Alex Norris

20

Clause **1,** page **2**, line **8**, at end insert "for a period of three years following the day on which this Act is passed."

Member's explanatory statement

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

All line references relate to the large print version of the Bill

Alex Norris

21

Clause **1,** page **3**, line **5**, 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

19

Clause **2,** page **4**, line **12**, 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

22

Clause **8,** page **12**, line **11**, 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

23

Clause **12,** page **17**, line **7**, 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).

All line references relate to the large print version of the Bill

Secretary Matt Hancock

1

Clause **14,** page **20**, line **7**, leave out "efficacy" and insert "performance, including the clinical effectiveness,"

Member's explanatory statement

This amendment clarifies the matters relating to medical devices the recording of information about which may be the subject of provision in regulations under Clause 12(1).

Secretary Matt Hancock

2

Clause **35,** page **42**, line **5**, at end insert—

"(2) A person to whom information is disclosed under regulations under section (*Information systems*) commits an offence if the person uses or discloses that information in contravention of those regulations."

Member's explanatory statement

This amendment and Amendment 3 provide that a person who discloses information in breach of regulations made under the new clause inserted by NC1 commits a criminal offence.

Secretary Matt Hancock

3

Clause **35,** page **42**, line **6**, after "subsection (1)" insert "or (2)"

Member's explanatory statement

See the explanatory statement for Amendment 2.

Secretary Matt Hancock

4

Clause **38,** page **49**, line **15**, leave out "and 12(1)" and insert ", 12(1) and (*Information systems*)(1)"

Member's explanatory statement

This amendment enables regulations made under the new clause inserted by NC1 to make consequential and other provision.

Secretary Matt Hancock

5

Clause **40,** page **50**, line **9**, leave out "sections 1(1), 8(1) or 12(1), or paragraph 9 of Schedule 1" and insert "a provision of Part 1, 2 or 3"

Member's explanatory statement

This amendment and Amendment 6 have the effect that the Secretary of State is required to consult

before making regulations under the new clause inserted by NC1.

Secretary Matt Hancock

6

Clause **40,** page **51**, line **6**, after "section 12(1)" insert "or (I*nformation systems*)(1),"

Member's explanatory statement

See the explanatory statement for Amendment 5.

Secretary Matt Hancock

7

Clause **41,** page **51**, line **9**, leave out "section 1(1), 8(1) or 12(1), or paragraph 9 of Schedule 1," and insert "a provision of Part 1, 2 or 3"

Member's explanatory statement

This amendment has the effect that regulations made under the new clause inserted by NC1 are to be made statutory instrument.

Secretary Matt Hancock

8

Clause **41,** page **51**, line **24**, leave out “section 1(1), 8(1) or 12(1)” and insert “a provision of Part 1, 2 or 3”

Member’s explanatory statement

This amendment and Amendments 9 to 17 enable regulations under powers in the Bill which are subject to negative procedure to be combined in a single statutory instrument with regulations under powers which are subject to affirmative procedure, or with regulations under powers in other legislation which are subject to negative procedure.

Secretary Matt Hancock

9

Clause **41,** page **52**, line **13**, leave out “to which subsection (9) applies”

Member’s explanatory statement

See the explanatory statement for Amendment 8.

Secretary Matt Hancock

10

Clause **41,** page **52**, line **15**, at end insert “if the only regulations under a provision of Part 1, 2 or 3 that it

contains are regulations to which subsection (9) applies”

Member’s explanatory statement

See the explanatory statement for Amendment 8.

Secretary Matt Hancock

11

Clause **41,** page **52**, line **17**, leave out “to which subsection (9) applies”

Member’s explanatory statement

See the explanatory statement for Amendment 8.

Secretary Matt Hancock

12

Clause **41,** page **52**, line **20**, at end insert “if the only regulations under section 1(1) or 8(1) that they contain are regulations to which subsection (9) applies”

Member’s explanatory statement

See the explanatory statement for Amendment 8.

Secretary Matt Hancock

13

Clause **41,** page **52**, line **23**, leave out “to which subsection (9) applies”

Member's explanatory statement
See the explanatory statement for Amendment 8.

Secretary Matt Hancock

14

Clause **41,** page **52**, line **29**, at end insert—

", if the only regulations under a provision of Part 1, 2 or 3 that it contains are regulations to which subsection (9) applies"

Member's explanatory statement
See the explanatory statement for Amendment 8.

Secretary Matt Hancock

15

Clause **41,** page **53**, line **1**, after "to" insert "—

(a) "

Member's explanatory statement
See the explanatory statement for Amendment 8.

Secretary Matt Hancock

16

Clause **41,** page **53**, line **17**, at end insert ", and

(b) regulations under paragraph 9 of Schedule 1"

Member's explanatory statement
See the explanatory statement for Amendment 8.

All line references relate to the large print version of the Bill

Secretary Matt Hancock

17

Clause **41,** page **53**, line **18**, leave out subsection (10)

Member's explanatory statement

See the explanatory statement for Amendment 8.

Secretary Matt Hancock

18

Clause **43,** page **54**, line **17**, at end insert ", and

(d) section (Information systems)"

Member's explanatory statement

This amendment provides for the new clause inserted by NC1 to come into force two months after the Bill is passed.

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:

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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.
