

Medicines and Medical Devices Bill

AMENDMENTS
TO BE MOVED
IN GRAND COMMITTEE

Clause 1

LORD SHARKEY

Page 1, line 6, at end insert—

- “() Regulations made under subsection (1) are subject, in relation to regulations made by the Secretary of State, to the super-affirmative procedure set out in section (*Super-affirmative procedure*), in relation to regulations made by a Northern Ireland department, to section (*Super-affirmative procedure: Northern Ireland*), and, in relation to regulations of the Secretary of State and a Northern Ireland department acting jointly, to both.”

Member’s explanatory statement

This amendment, and the amendments to page 5 line 12, page 7 line 22 and page 9 line 27 in the name of Lord Sharkey, replace the existing affirmative procedure with a super-affirmative procedure in order to increase parliamentary scrutiny.

Clause 8

LORD SHARKEY

Page 5, line 12, at end insert—

- “() Regulations made under subsection (1) are subject, in relation to regulations made by the Secretary of State, to the super-affirmative procedure set out in section (*Super-affirmative procedure*), in relation to regulations made by a Northern Ireland department, to section (*Super-affirmative procedure: Northern Ireland*), and, in relation to regulations of the Secretary of State and a Northern Ireland department acting jointly, to both.”

Member’s explanatory statement

This amendment, and the amendments to page 1 line 6, page 7 line 22 and page 9 line 27 in the name of Lord Sharkey, replace the existing affirmative procedure with a super-affirmative procedure in order to increase parliamentary scrutiny.

Clause 12

LORD SHARKEY

Page 7, line 22, at end insert –

“() Regulations made under subsection (1) are subject, in relation to regulations made by the Secretary of State, to the super-affirmative procedure set out in section (*Super-affirmative procedure*), in relation to regulations made by a Northern Ireland department, to section (*Super-affirmative procedure: Northern Ireland*), and, in relation to regulations of the Secretary of State and a Northern Ireland department acting jointly, to both.”

Member’s explanatory statement

This amendment, and the amendments to page 1, line 6, page 5 line 12 and page 9 line 27 in the name of Lord Sharkey, replace the existing affirmative procedure with a super-affirmative procedure in order to increase parliamentary scrutiny.

LORD FREYBERG

LORD CLEMENT-JONES

Page 7, line 28, at end insert –

“() Within 12 months of this section coming into force, the Secretary of State must initiate a comprehensive technical review of the definition of “medical device” under the Medical Devices Regulations 2002 with a view to addressing the inclusion of artificial intelligence software and algorithms including methodologies for the interpretation of data and associated technical architecture in medical devices.”

Member’s explanatory statement

This amendment seeks to improve how the Bill addresses new technologies which have significant potential for harm, aligning with and improving on the EU and US equivalents.

Clause 16

LORD SHARKEY

Page 9, line 27, at end insert –

“() Regulations made under subsection (1) are subject, in relation to regulations made by the Secretary of State, to the super-affirmative procedure set out in section (*Super-affirmative procedure*), in relation to regulations made by a Northern Ireland department, to section (*Super-affirmative procedure: Northern Ireland*), and, in relation to regulations of the Secretary of State and a Northern Ireland department acting jointly, to both.”

Member’s explanatory statement

This amendment, and the amendments to page 1, line 6, page 5 line 12 and page 7 line 22 in the name of Lord Sharkey, replace the existing affirmative procedure with a super-affirmative procedure in order to increase parliamentary scrutiny.

Clause 37

LORD FREYBERG
LORD CLEMENT-JONES

Page 21, line 46, leave out “(7)” and insert “(8)”

Page 22, line 2, at end insert –

“() In regulation 2 (interpretation), in paragraph (1) in the definition of “medical device”, after “software” insert “and algorithms including methodologies for the interpretation of data, and associated technical architecture,”

Member’s explanatory statement

This amendment updates the definition of medical device to bring it in line with the EU and US regulation, acknowledging the progress of technology beyond the Medical Devices Regulations 2002.

After Clause 42

LORD SHARKEY

Insert the following new Clause –

“Super-affirmative procedure

- (1) For the purposes of section 1(1), section 8(1), section 12(1) and section 16(1), the “super-affirmative procedure” is as follows.
- (2) The Secretary of State must lay before Parliament –
 - (a) a draft of the regulations, and
 - (b) a document which explains the draft regulations.
- (3) Where a draft of the regulations is laid before Parliament under subsection (2), no statutory instrument containing the regulations is to be laid before Parliament until after the expiry of the 30-day period.
- (4) The Secretary of State must request a committee of either House whose remit includes health, science or technology to report on the draft regulations within the 30-day period.
- (5) In preparing a draft statutory instrument containing the regulations, the Secretary of State must take account of –
 - (a) any representations,
 - (b) any resolution of either House of Parliament, and
 - (c) any recommendations of a committee under subsection (4),made within the 30-day period with regard to the draft regulations.
- (6) If, after the 30-day period, the Secretary of State wishes to make regulations in the terms of the draft or a revised draft, he or she must lay before Parliament a statement –
 - (a) stating whether any representations, resolutions or recommendations were made under subsection (5);
 - (b) giving details of any representations, resolutions or recommendations so made; and

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- (c) explaining any changes made in any revised draft of the regulations.
- (7) The Secretary of State may make a statutory instrument containing the regulations (whether or not revised) if, after the laying of the statement required under subsection (6), a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.
- (8) In this section, reference to “the 30-day period” in relation to any draft regulations is to the period of 30 days beginning with the day on which the original draft regulations were laid before Parliament.
- (9) For the purposes of subsection (8) no account is to be taken of any time during which Parliament is dissolved or prorogued or during which either House is adjourned for more than four days.”

Insert the following new Clause –

“Super-affirmative procedure: Northern Ireland

- (1) For the purposes of section 1(1), section 8(1), section 12(1) and section 16(1), the “super-affirmative resolution procedure” in the Northern Ireland Assembly is as follows.
- (2) The Department must request a committee of the Assembly whose remit includes health, science or technology to report on the draft order within the 30-day period.
- (3) A Northern Ireland Department must take account of –
 - (a) any representations,
 - (b) any resolution of the Assembly, and
 - (c) any recommendations of a committee under subsection (2),
 made within the 30-day period.
- (4) If, after the 30-day period, the Department wishes to make an order in the terms of the draft, it must lay before the Assembly a statement –
 - (a) stating whether any representations were made under subsection (2)(a); and
 - (b) if any representations were so made, giving details of them.
- (5) The Department may after the laying of such a statement lay before the Assembly for approval by affirmative resolution the draft order in its initial form, or a revised draft order together with an explanation of the changes made.
- (6) In this section, reference to the “30-day period” in relation to any draft order is to the period of 30 days beginning with the day on which the original draft order was laid before the Assembly.
- (7) For the purposes of subsection (6) no account is to be taken of any time during which the Assembly is dissolved or adjourned for more than four days.”

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15 September 2020
