Medicines and Medical Devices Bill

COMMONS AMENDMENTS, DISAGREEMENTS AND AMENDMENTS IN LIEU

[*The page and line numbers refer to HL Bill 116, the bill as first printed for the Lords, or to the Lords Amendment*]

Clause 1

LORDS AMENDMENT 2

2 Page 1, line 6, at end insert "for a period of three years beginning with the day on which this Act is passed."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 2 but propose Amendments 50A, 50B and 50C in lieu. [See below after Lords Amendment 50]

LORDS AMENDMENT 3

3 Page 1, line 6, at end insert—

"(1A) Regulations made under subsection (1) that introduce significant new policy or significant changes to existing policy 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."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 3 but propose Amendments 50A, 50B and 50C in lieu.

After Clause 6

LORDS AMENDMENT 11

11 Insert the following new Clause—

"Disclosure of information in accordance with international agreements

(1) This section applies to information which a relevant authority holds in connection with human medicines.

(2) The relevant authority may disclose information to a relevant person outside the United Kingdom where required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of human medicines.

(3) Where information is disclosed in accordance with subsection (2) such disclosure will only be permitted where—

(a) it is required as part of international cooperation for pharmacovigilance; or

(b) it is in the public interest.

(4) The relevant authority may not disclose commercially sensitive information in reliance on subsection (2) unless the relevant authority—

(a) considers that it is necessary to do so for the purpose mentioned in that subsection, and

(b) is satisfied that the making of the disclosure is proportionate to what is sought to be achieved by it.

(5) Except as provided by subsection (7), the disclosure of information in accordance with this section does not breach—

(a) an obligation of confidence owed by the person making the disclosure, or

(b) any other restriction on the disclosure of the information (however imposed).

(6) Nothing in this section authorises a disclosure of patient information without the consent of the individual to whom that information relates.

(7) Nothing in this section authorises a disclosure of information which—

(a) contravenes the data protection legislation (but in determining whether a disclosure would do so, take into account the powers conferred by this section), or

(b) is prohibited by any of Parts 1 to 7 or Chapter 1 of Part 9 of the Investigatory Powers Act 2016.

(8) This section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

(9) In this section—

"commercially sensitive information" means commercial information whose disclosure the relevant authority thinks might significantly harm the legitimate business interests of the undertaking to which it relates;

"data protection legislation" has the meaning given by section 3(9) of the Data Protection Act 2018;

"patient information" means information (however recorded) which—

(a) relates to—

(i) the physical or mental health or condition of an individual,

(ii) the diagnosis of an individual's condition, or

(iii) an individual's care or treatment,

or is (to any extent) derived directly or indirectly from information relating to any of those matters, and

(b) identifies the individual or enables the individual to be identified (whether by itself or in combination with other information);

"relevant authority" means—

(a) the Secretary of State, or

(b) the Department of Health in Northern Ireland;

"relevant person" means—

(a) the government of a country or territory outside the United Kingdom;

(b) a person who exercises functions on behalf of such a government;

(c) any other person who exercises functions or provides services relating to human medicines in a country or territory outside the United Kingdom;

(d) an international organisation that exercises functions or provides services relating to human medicines."

COMMONS AMENDMENTS

The Commons agree with the Lords in their Amendment 11 and propose Amendments 11A, 11B, 11C and 11D as amendments thereto—

11A Line 6, after "where" insert "—

(a) the disclosure is"

11B Line 8, at end insert ", and

(b) the relevant authority considers that the disclosure is in the public interest."

11C Line 9, leave out subsection (3)

11D Line 20, leave out "subsection (7)" and insert "subsections (6) and (7)"

LORDS AMENDMENT 12

12 Insert the following new Clause—

"Requirement for draft consolidated legislation: human medicines

The Secretary of State must, within the period of three years beginning with the day on which this Act is passed, publish draft legislation consolidating the regulatory regime as it applies to human medicines."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 12 but propose Amendments 50A, 50B and 50C in lieu.

Clause 8

LORDS AMENDMENT 13

13 Page 5, line 12, at end insert "for a period of three years beginning with the day on which this Act is passed."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 13 but propose Amendments 50A, 50B and 50C in lieu.

LORDS AMENDMENT 14

14 Page 5, line 12, at end insert—

"(1A) Regulations made under subsection (1) that introduce significant new policy or significant changes to existing policy 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."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 14 but propose Amendments 50A, 50B and 50C in lieu.

After Clause 10

LORDS AMENDMENT 22

22 Insert the following new Clause—

"Disclosure of information in accordance with international agreements

(1) This section applies to information which a relevant authority holds in connection with veterinary medicines.

(2) The relevant authority may disclose information to a relevant person outside the United Kingdom where required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of veterinary medicines.

(3) Where information is disclosed in accordance with subsection (2) such disclosure will only be permitted where—

(a) it is required as part of international cooperation for pharmacovigilance; or

(b) it is in the public interest.

(4) The relevant authority may not disclose commercially sensitive information in reliance on subsection (2) unless the relevant authority—

(a) considers that it is necessary to do so for the purpose mentioned in that subsection, and

(b) is satisfied that the making of the disclosure is proportionate to what is sought to be achieved by it.

(5) Except as provided by subsection (6), the disclosure of information in accordance with this section does not breach—

(a) an obligation of confidence owed by the person making the disclosure, or

(b) any other restriction on the disclosure of the information (however imposed).

(6) Nothing in this section authorises a disclosure of information which—

(a) contravenes the data protection legislation (but in determining whether a disclosure would do so, take into account the powers conferred by this section), or

(b) is prohibited by any of Parts 1 to 7 or Chapter 1 of Part 9 of the Investigatory Powers Act 2016.

(7) This section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

(8) In this section—

"commercially sensitive information" means commercial information whose disclosure the relevant authority thinks might significantly harm the legitimate business interests of the undertaking to which it relates;

"data protection legislation" has the meaning given by section 3(9) of the Data Protection Act 2018;

"relevant authority" means—

(a) the Secretary of State, or

(b) the Department of Agriculture, Environment and Rural Affairs in Northern Ireland;

"relevant person" means—

(a) the government of a country or territory outside the United Kingdom;

(b) a person who exercises functions on behalf of such a government;

(c) any other person who exercises functions or provides services relating to veterinary medicines in a country or territory outside the United Kingdom;

(d) an international organisation that exercises functions or provides services relating to veterinary medicines."

COMMONS AMENDMENTS

The Commons agree with the Lords in their Amendment 22 and propose Amendments 22A, 22B and 22C as amendments thereto—

22A Line 6, after "where" insert "—

(a) the disclosure is"

22B Line 8, at end insert ", and

(b) the relevant authority considers that the disclosure is in the public interest."

22C Line 9, leave out subsection (3)

LORDS AMENDMENT 23

23 Insert the following new Clause—

"Requirement for draft consolidated legislation: veterinary medicines

The Secretary of State must, within the period of three years beginning with the day on which this Act is passed, publish draft legislation consolidating the regulatory regime as it applies to veterinary medicines."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 23 but propose Amendments 50A, 50B and 50C in lieu.

Clause 12

LORDS AMENDMENT 24

24 Page 7, line 22, at end insert "for a period of three years beginning with the day on which this Act is passed"

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 24 but propose Amendments 50A, 50B and 50C in lieu.

LORDS AMENDMENT 25

25 Page 7, line 22, at end insert—

"(1A) Regulations made under subsection (1) that introduce significant new policy or significant changes to existing policy are subject to the super-affirmative procedure set out in section (*Super-affirmative procedure*)."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 25 but propose Amendments 50A, 50B and 50C in lieu.

Clause 16

LORDS AMENDMENT 30

30 Page 9, line 27, at end insert—

"(1A) Regulations made under subsection (1) that introduce significant new policy or significant changes to existing policy are subject to the super-affirmative procedure set out in section (*Super-affirmative procedure*)."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 30 but propose Amendments 50A, 50B and 50C in lieu.

Clause 35

LORDS AMENDMENT 32

32 Page 19, line 33, at end insert—

"(4A) The Secretary of State may disclose information to a relevant person outside the United Kingdom where required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of medical devices.

(4B) But subsection (4A) does not authorise a disclosure of patient information without the consent of the individual to whom that information relates.

(4C) Where information is disclosed in accordance with subsection (4A) such disclosure will only be permitted where—

(a) it is required as part of international cooperation in monitoring the performance and safety of medical devices; or

(b) it is in the public interest."

COMMONS AMENDMENTS

The Commons agree with the Lords in their Amendment 32 and propose Amendments 32A, 32B and 32C as amendments thereto—

32A Line 3, after "where" insert "—

(a) the disclosure is"

32B Line 5, at end insert ", and

(b) the relevant authority considers that the disclosure is in the public interest."

32C Line 8, leave out subsection (4C)

After Clause 37

LORDS AMENDMENT 40

40 Insert the following new Clause—

"Requirement for draft consolidated legislation: medical devices

The Secretary of State must, within the period of three years beginning with the day on which this Act is passed, publish draft legislation consolidating the regulatory regime as it applies to medical devices."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 40 but propose Amendments 50A, 50B and 50C in lieu.

Clause 42

LORDS AMENDMENT 48

48 Page 24, line 36, leave out subsections (3) to (9) and insert—

"(3) The procedure for making regulations under Part A1, 1, 2 or 3 is to be determined in accordance with this table and subsection (4)—

If the regulations contain provision made in reliance on	*the regulations are subject to*
section 5(1)(a)	the negative procedure
section 10(1)(a)	the negative procedure
section 14(1)(a)	the negative procedure
paragraph 9 of Schedule 1	the negative procedure
section 6	the made affirmative procedure, where the regulations contain a declaration that the person making them considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health
section 15	the made affirmative procedure, where the regulations contain a declaration that the Secretary of State considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health

(4) Provision that may be made by regulations subject to the negative procedure may be made by regulations subject to the draft affirmative procedure.

(5) Where regulations are subject to "the negative procedure"—

(a) in the case of regulations made by the Secretary of State acting alone, the statutory instrument containing the regulations is subject to annulment in pursuance of a resolution of either House of Parliament,

(b) in the case of regulations made by a Northern Ireland department acting alone, they are subject to negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954, and

(c) in the case of regulations made by the Secretary of State and a Northern Ireland department acting jointly, the statutory instrument containing the regulations is subject to—

(i) annulment in pursuance of a resolution of either House of Parliament, and

(ii) negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954.

(6) Where regulations are subject to the "draft affirmative procedure"—

(a) in the case of regulations made by the Secretary of State acting alone, the statutory instrument containing the regulations may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament,

(b) in the case of regulations made by a Northern Ireland department acting alone, they may not be made unless a draft of the regulations has been laid before and approved by a resolution of the Northern Ireland Assembly, and

(c) in the case of regulations made by the Secretary of State and a Northern Ireland department acting jointly, the statutory instrument containing the regulations may not be made unless a draft of the instrument has been laid before and approved by a resolution of—

(i) each House of Parliament, and

(ii) the Northern Ireland Assembly.

(7) Where regulations are subject to the "made affirmative procedure"—

(a) in the case of regulations made by the Secretary of State acting alone, the statutory instrument containing the regulations—

(i) must be laid before Parliament after being made, and

(ii) ceases to have effect at the end of the period of 40 days beginning with the day on which the instrument is made unless, during that period, the instrument is approved by a resolution of each House of Parliament,

(b) in the case of regulations made by the Department of Health in Northern Ireland acting alone, they—

(i) must be laid before the Northern Ireland Assembly after being made, and

(ii) cease to have effect at the end of the period of 40 days beginning with the day on which they are made unless, during that period, the regulations are approved by a resolution of the Assembly, and

(c) in the case of regulations made by the Secretary of State and the Department of Health in Northern Ireland acting jointly, the statutory instrument containing the regulations—

(i) must be laid before Parliament and the Northern Ireland Assembly after being made, and

(ii) ceases to have effect at the end of the period of 40 days beginning with the day on which the instrument is made unless, during that period, the instrument is approved by a resolution of each House of Parliament and by a resolution of the Assembly.

(8) In calculating the period of 40 days for the purposes of subsection (7)(a)(ii) or (c)(ii) in relation to Parliament, no account is to be taken of any time during which—

(a) Parliament is dissolved or prorogued, or

(b) either House of Parliament is adjourned for more than 4 days.

(9) In calculating the period of 40 days for the purposes of subsection (7)(b)(ii) or (c)(ii) in relation to the Northern Ireland Assembly, no account is to be taken of any time during which the Assembly is—

(a) dissolved,

(b) in recess for more than 4 days, or
(c) adjourned for more than 6 days.

(10) If regulations cease to have effect as a result of subsection (7) that—
(a) does not affect the validity of anything previously done under the regulations, and
(b) does not prevent the making of new regulations."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 48 but propose Amendments 50A, 50B and 50C in lieu.

After Clause 42

LORDS AMENDMENT 49

49 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
(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."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 49 but propose Amendments 50A, 50B and 50C in lieu.

LORDS AMENDMENT 50

50 Insert the following new Clause—

"Super-affirmative procedure: Northern Ireland

(1) For the purposes of section 1(1) and section 8(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 regulations 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 regulations in the terms of the draft, it must lay before the Assembly a statement—
  (a) stating whether any representations were made under subsection (3)(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 regulations in their original form, or revised draft regulations together with an explanation of the changes made.

(6) In this section, reference to the "30-day period" in relation to any draft is to the period of 30 days beginning with the day on which the original draft 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."

COMMONS DISAGREEMENT AND AMENDMENTS IN LIEU

The Commons disagree to Lords Amendment 50 but propose Amendments 50A, 50B and 50C in lieu—

Clause 42

50A Page 24, line 36, leave out subsections (3) to (9) and insert—

"(3) The procedure for making regulations under Part A1, 1, 2 or 3 is to be determined in accordance with this table and subsection (4)—

If the regulations contain provision made in reliance on	*the regulations are subject to*
section 5(1)(a)	the negative procedure
section 10(1)(a)	the negative procedure
section 14(1)(a)	the negative procedure
paragraph 9 of Schedule 1	the negative procedure
section 6	(a) the made affirmative procedure, where the regulations contain a declaration that the person making them considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health (b) the draft affirmative procedure in any other case
section 15	(a) the made affirmative procedure, where the regulations contain a declaration that the person making them considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health (b) the draft affirmative procedure in any other case
any other provision of Part A1, 1, 2 or 3	the draft affirmative procedure

(4) Provision that may be made by regulations subject to the negative procedure may be made by regulations subject to the draft affirmative procedure.

(5) Where regulations are subject to "the negative procedure"—

(a) in the case of regulations made by the Secretary of State acting alone, the statutory instrument containing the regulations is subject to annulment in pursuance of a resolution of either House of Parliament,

(b) in the case of regulations made by a Northern Ireland department acting alone, they are subject to negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954, and

(c) in the case of regulations made by the Secretary of State and a Northern Ireland department acting jointly, the statutory instrument containing the regulations is subject to—

(i) annulment in pursuance of a resolution of either House of Parliament, and

(ii) negative resolution within the meaning given by section 41(6) of the Interpretation Act (Northern Ireland) 1954.

(6) Where regulations are subject to the "draft affirmative procedure"—

(a) in the case of regulations made by the Secretary of State acting alone, the statutory instrument containing the regulations may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament,

(b) in the case of regulations made by a Northern Ireland department acting alone, they may not be made unless a draft of the regulations has been laid before and approved by a resolution of the Northern Ireland Assembly, and

(c) in the case of regulations made by the Secretary of State and a Northern Ireland department acting jointly, the statutory instrument containing the regulations may not be made unless a draft of the instrument has been laid before and approved by a resolution of—

(i) each House of Parliament, and

(ii) the Northern Ireland Assembly.

(7) Where regulations are subject to the "made affirmative procedure"—

(a) in the case of regulations made by the Secretary of State acting alone, the statutory instrument containing the regulations—

(i) must be laid before Parliament after being made, and

(ii) ceases to have effect at the end of the period of 40 days beginning with the day on which the instrument is made unless, during that period, the instrument is approved by a resolution of each House of Parliament,

(b) in the case of regulations made by a Northern Ireland department acting alone, they—

(i) must be laid before the Northern Ireland Assembly after being made, and

(ii) cease to have effect at the end of the period of 40 days beginning with the day on which they are made unless, during that period, the regulations are approved by a resolution of the Assembly, and

(c) in the case of regulations made by the Secretary of State and a Northern Ireland department acting jointly, the statutory instrument containing the regulations—

(i) must be laid before Parliament and the Northern Ireland Assembly after being made, and

(ii) ceases to have effect at the end of the period of 40 days beginning with the day on which the instrument is made unless, during that period, the instrument is approved by a resolution of each House of Parliament and by a resolution of the Assembly.

(8) In calculating the period of 40 days for the purposes of subsection (7)(a)(ii) or (c)(ii) in relation to Parliament, no account is to be taken of any time during which—

(a) Parliament is dissolved or prorogued, or

(b) either House of Parliament is adjourned for more than 4 days.

(9) In calculating the period of 40 days for the purposes of subsection (7)(b)(ii) or (c)(ii) in relation to the Northern Ireland Assembly, no account is to be taken of any time during which the Assembly is—

(a) dissolved,

(b) in recess for more than 4 days, or

(c) adjourned for more than 6 days.

(10) If regulations cease to have effect as a result of subsection (7) that—

(a) does not affect the validity of anything previously done under the regulations, and

(b) does not prevent the making of new regulations."

After Clause 42

50B Insert the following new Clause—

"PART 4A

REPORT ON OPERATION OF MEDICINES AND MEDICAL DEVICES LEGISLATION

Report on operation of medicines and medical devices legislation

(1) The Secretary of State must, before the end of the relevant period, publish a report on the operation of medicines and medical devices legislation.

(2) The report must, in particular, include an assessment of whether—

(a) some or all medicines and medical devices legislation should be consolidated or otherwise restructured,

(b) provisions of medicines and medical devices legislation should be included in regulations or Acts of Parliament, and

(c) powers to make regulations should be modified or repealed.

(3) In preparing the report, the Secretary of State must take into account any report relating to the operation of medicines and medical devices legislation made by a Parliamentary Committee.

(4) The Secretary of State must lay a copy of the report before Parliament.

(5) In this section—

"medicines and medical devices legislation" means—

(a) the law relating to human medicines within the meaning of section 7 (interpretation);

(b) the Veterinary Medicines Regulations 2013 (S.I. 2013/2033);

(c) the Medical Devices Regulations 2002 (S.I. 2002/618);

(d) Parts 1 to 4 of this Act;

(e) regulations made under those Parts;

"Parliamentary Committee" means a committee of the House of Commons or of the House of Lords or a joint committee of both Houses;

"relevant period" means the period of 5 years beginning with the day on which this Act is passed."

Clause 44

50C Page 26, line 8, at end insert—

"(ha) Part 4A."

Medicines and Medical Devices Bill

COMMONS AMENDMENTS, DISAGREEMENTS AND AMENDMENTS IN LIEU

27th January 2021

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