House of Commons

# NOTICES OF AMENDMENTS

**given up to and including**

**Monday 25 January 2021**

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## CONSIDERATION OF LORDS AMENDMENTS

## MEDICINES AND MEDICAL DEVICES BILL

*On Consideration of Lords Amendments to the Medicines and Medical Devices Bill*

Lords Amendment No. **2**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

Lords Amendment No. **3**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

**Medicines and Medical Devices Bill,** *continued*

Lords Amendment No. **11**

As Amendments to the Lords Amendment:—

Secretary Matt Hancock

**(a)**

Line **6**, after "where" insert "—

(a) the disclosure is"

**(b)**

Line **8**, at end insert ", and

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

**(c)**

Line **9**, leave out subsection (3)

**(d)**

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

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Lords Amendment No. **12**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

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Lords Amendment No. **13**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

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**Medicines and Medical Devices Bill,** *continued*

Lords Amendment No. **14**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

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Lords Amendment No. **22**

As Amendments to the Lords Amendment:—

Secretary Matt Hancock

**(a)**

Line **6**, after "where" insert "—

(a) the disclosure is"

**(b)**

Line **8**, at end insert ", and

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

**(c)**

Line **9**, leave out subsection (3)

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Lords Amendment No. **23**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

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Lords Amendment No. **24**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

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**Medicines and Medical Devices Bill,** *continued*

Lords Amendment No. **25**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

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Lords Amendment No. **30**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

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Lords Amendment No. **32**

As Amendments to the Lords Amendment:—

Secretary Matt Hancock

**(a)**

Line **3**, after "where" insert "—

(a) the disclosure is"

**(b)**

Line **5**, at end insert ", and

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

**(c)**

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

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Lords Amendment No. **40**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

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**Medicines and Medical Devices Bill,** *continued*

Lords Amendment No. **48**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

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Lords Amendment No. **49**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

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Lords Amendment No. **50**

Secretary Matt Hancock

To move, That this House disagrees with the Lords in their Amendment.

Secretary Matt Hancock

To move the following Amendments to the Bill in lieu of Lords Amendments 2, 3, 12, 13, 14, 23, 24, 25, 30, 40, 48, 49 and 50:—

**(a)**

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 |

**Medicines and Medical Devices Bill,** *continued*

| *If the regulations contain provision made in reliance on* | *the regulations are subject to* |
|---|---|
| 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<br><br>(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<br><br>(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

**Medicines and Medical Devices Bill,** *continued*

(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."

**(b)**

After Clause 42, 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—

**Medicines and Medical Devices Bill,** *continued*

(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."

**(c)**

Page **26**, line **8**, at end insert—

"(ha) Part 4A."