Medicines and Medical Devices Bill

AMENDMENTS

TO BE MOVED

IN GRAND COMMITTEE

Clause 1

LORD BETHELL

Page 1, line 6, at end insert—

"(1A) The appropriate authority may only make regulations under subsection (1) if satisfied that they would promote the health and safety of the public."

Member's explanatory statement
This amendment provides that the appropriate authority may only make regulations under subsection (1) of Clause 1 if satisfied that they would promote the health and safety of the public.

Page 1, line 7, leave out "making regulations under subsection (1)" and insert "considering whether they would"

Member's explanatory statement
This amendment requires the appropriate authority to have regard to the factors mentioned in subsection (2)(a), (b) and (c) of Clause 1 in considering whether regulations made under subsection (1) would promote the health and safety of the public.

Page 1, line 11, leave out paragraph (c) and insert—

"(c) the likelihood of the relevant part of the United Kingdom being seen as an attractive or favourable place in which to conduct clinical trials or supply human medicines."

Member's explanatory statement
This amendment clarifies what was meant by the version of Clause 1(2)(c) in the Bill as brought from the House of Commons.

Clause 2

BARONESS FINLAY OF LLANDAFF
LORD HUNT OF KINGS HEATH

Page 2, line 23, at end insert—

"(o) developing rapid provisional two-year licenses."

Clause 5

LORD BETHELL

Page 3, line 35, leave out from "regulations," to "or" in line 36

Member's explanatory statement
See the explanatory statement for the amendment in the Minister's name inserting new subsection (1A) into Clause 5.

Page 3, line 39, at end insert—

"(1A) Regulations under section 1(1) may not provide for an offence to be punishable with a sentence of imprisonment of more than two years."

Member's explanatory statement
This amendment, and the other amendment to Clause 5 in the Minister's name, ensures that regulations under Clause 1(1) may not provide for any offence to be punishable with a sentence of imprisonment of more than two years.

After Clause 6

LORD BETHELL

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 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) 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.

(4) Except as provided by subsection (5), 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).

After Clause 6 - *continued*

(5) 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.

(6) 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;

"relevant authority" means—

(a) the Secretary of State, or

(b) the Department of Health in Northern Ireland;

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

Member's explanatory statement

This new Clause makes clear that information held by the Secretary of State or the Department of Health in Northern Ireland in connection with human medicines can be disclosed, subject to certain restrictions, to persons outside the United Kingdom in order to give effect to a relevant international agreement or arrangement.

Clause 8

LORD BETHELL

Page 5, line 12, at end insert—

"(1A) The appropriate authority may only make regulations under subsection (1) if satisfied that they would promote one or more of the following—

(a) the health and welfare of animals;

(b) the health and safety of the public;

(c) the protection of the environment."

Member's explanatory statement

This amendment provides that the appropriate authority may only make regulations under subsection (1) of Clause 8 if satisfied that they would promote the health or welfare of animals, the health and safety of the public or the protection of the environment.

Page 5, line 13, leave out "making regulations under subsection (1)" and insert "considering whether they would"

Member's explanatory statement

This amendment requires the appropriate authority to have regard to the factors mentioned in subsection (2)(a), (b) and (c) of Clause 8 in considering whether regulations under subsection (1) would promote the health or welfare of animals, the health and safety of the public or the protection of the environment.

Page 5, line 15, leave out "in relation to animals, humans and the environment"

Member's explanatory statement
This amendment is consequential on the amendment in the Minister's name inserting a new subsection after subsection (1) of Clause 8.

Page 5, line 18, leave out paragraph (c) and insert—

"(c) the likelihood of the relevant part of the United Kingdom being seen as an attractive or favourable place in which to develop or supply veterinary medicines."

Member's explanatory statement
This amendment clarifies what was meant by the version of Clause 8(2)(c) in the Bill as brought from the House of Commons.

Clause 10

LORD BETHELL

Page 6, line 27, leave out from "regulations," to end of line 28

Member's explanatory statement
See the explanatory statement for the amendment in the Minister's name inserting new subsection (1A) into Clause 10.

Page 6, line 35, at end insert—

"(1A) Regulations under section 8(1) may not provide for an offence to be punishable with a sentence of imprisonment of more than two years."

Member's explanatory statement
This amendment, and the other amendment to clause 10 in the Minister's name, ensures that regulations under Clause 8(1) may not provide for any offence to be punishable with a sentence of imprisonment of more than two years.

After Clause 10

LORD BETHELL

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 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) 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.

After Clause 10 - *continued*

(4) Except as provided by subsection (5), 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).

(5) 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.

(6) 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;

"relevant authority" means—

(a) the Secretary of State, or

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

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

Member's explanatory statement

This new Clause makes clear that information held by the Secretary of State or the Department of Agriculture, Environment and Rural Affairs in Northern Ireland in connection with veterinary medicines can be disclosed, subject to certain restrictions, to persons outside the United Kingdom in order to give effect to a relevant international agreement or arrangement.

Clause 12

LORD BETHELL

Page 7, line 22, at end insert—

"(1A) The Secretary of State may only make regulations under subsection (1) if satisfied that they would promote the health and safety of the public."

Member's explanatory statement

This amendment provides that the Secretary of State may only make regulations under subsection (1) of Clause 12 if satisfied that they would promote the health and safety of the public.

Page 7, line 23, leave out "making regulations under subsection (1)" and insert "considering whether they would"

Member's explanatory statement
This amendment requires the Secretary of State to have regard to the factors mentioned in subsection (2)(a), (b) and (c) of Clause 12 in considering whether regulations under subsection (1) would promote the health and safety of the public.

Page 7, line 27, leave out paragraph (c) and insert—

"(c) the likelihood of the United Kingdom being seen as an attractive or favourable place in which to develop or supply medical devices."

Member's explanatory statement
This amendment clarifies what was meant by the version of Clause 12(2)(c) in the Bill as brought from the House of Commons.

Clause 35

LORD BETHELL

Page 19, line 33, at end insert—

"(4A) The Secretary of State may disclose information to a 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."

Member's explanatory statement
This amendment makes clear that information held by the Secretary of State in connection with medical devices can be disclosed, subject to certain restrictions, to persons outside the United Kingdom in order to give effect to a relevant international agreement or arrangement.

Page 19, line 35, leave out "or (4)" and insert ", (4) or (4A)"

Member's explanatory statement
This amendment is consequential on amendment in the Minister's name inserting a new subsection into Clause 35.

Page 19, line 37, leave out "or (4)" and insert ", (4) or (4A)"

Member's explanatory statement
This amendment is consequential on the amendment in the Minister's name inserting a new subsection into Clause 35.

Clause 41

LORD BETHELL

Page 24, line 9, leave out "consult such persons as the authority considers appropriate" and insert "carry out a public consultation.

(1A) In relation to proposed regulations under section 16(1), the Secretary of State must specifically consult—

(a) the Welsh Ministers,

(b) the Scottish Ministers, and

(c) the Department of Health in Northern Ireland.

Clause 41 - *continued*

(1B) In relation to proposed regulations under section 1(1), 8(1) or 12(1), the consultation document must include a summary of the relevant authority's assessment of the matters mentioned in section 1(1A) and (2), 8(1A) and (2) or 12(1A) and (2)(as the case may be)."

Member's explanatory statement
This amendment requires a relevant authority to carry out a public consultation before making regulations under any provision of Part 1, 2 or 3, and to set out the authority's assessment of any matter to which the authority must have regard in making the regulations, as well as requiring the Secretary of State to consult the devolved administrations in relation to regulations under clause 16(1).

After Clause 41

LORD BETHELL

Insert the following new Clause—

"Reporting requirements

(1) As soon as reasonably practicable after the end of each reporting period, the Secretary of State must lay before Parliament a report on the operation of any regulations made by the Secretary of State under sections 1(1), 8(1) and 12(1) that were in force at any time during the reporting period.

(2) In preparing a report, the Secretary of State must consult such persons as the Secretary of State considers appropriate.

(3) A report must include a summary of—

(a) any concerns raised, or proposals for change made, by a person consulted in accordance with subsection (2), and

(b) the Secretary of State's response to those concerns or proposals, including any plan the Secretary of State may have to make further regulations under section 1(1), 8(1) or 12(1).

(4) The reporting periods are—

(a) the period of 24 months beginning with the day on which the first set of regulations under section 1(1), 8(1) or 12(1) comes into force, and

(b) each successive period of 24 months."

Member's explanatory statement
This new Clause imposes reporting requirements on the Secretary of State in relation to the operation of regulations made under Clauses 1(1), 8(1) and 12(1).

Clause 42

LORD BETHELL

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

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

Clause 42 - *continued*

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 Secretary of State 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 in Part 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.

Clause 42 - *continued*

(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.

Clause 42 - *continued*

(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."

Member's explanatory statement

This amendment provides for urgent regulations made in reliance on clauses 6 and 15 (emergencies) to be subject to the made affirmative procedure rather than the negative procedure and for regulations under clauses 2(1)(j), (k) or (n) and 9(1)(f), (k) or (l) to be subject to the draft affirmative procedure rather than the negative procedure.

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IN GRAND COMMITTEE

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12 October 2020
