Medicines and Medical Devices Bill

AMENDMENTS

TO BE MOVED

ON REPORT

Before Clause 1

LORD BETHELL

Insert the following new Clause—

"PART A1

THE COMMISSIONER FOR PATIENT SAFETY

Establishment and core duties etc

(1) The Secretary of State must appoint a Commissioner for Patient Safety (referred to in this Part as "the Commissioner") to exercise the functions set out in this Part in relation to England.

(2) The Commissioner's core duties are to—

(a) promote the safety of patients with regard to the use of medicines and medical devices, and

(b) promote the importance of the views of patients and other members of the public in relation to the safety of medicines and medical devices.

(3) The Commissioner is not to be regarded as the servant or agent of the Crown or as enjoying any status, immunity or privilege of the Crown.

(4) Schedule (*Further provision about the Commissioner for Patient Safety*) makes further provision about the Commissioner."

Member's explanatory statement
This amendment inserts a new Clause which provides for the creation and core duties of a Commissioner for Patient Safety in relation to medicines and medical devices in England. The new Clause and the Schedule which it introduces would form a new Part, to appear before Part 1.

Clause 1

LORD BETHELL

Page 1, line 9, leave out subsection (2) and insert—

"(2) In making regulations under subsection (1), the appropriate authority's overarching objective must be safeguarding public health."

Member's explanatory statement
This amendment provides that the appropriate authority's overarching objective in making regulations under Clause 1 must be safeguarding public health.

Page 1, line 11, leave out "they would" and insert "regulations under subsection (1) would contribute to this objective"

Member's explanatory statement
This amendment is consequential on the amendment in the Minister's name substituting Clause 1(2).

Page 1, line 16, leave out "an attractive or" and insert "a"

Member's explanatory statement
This amendment omits the word "attractive" from Clause 1(3)(c).

Page 1, line 16, leave out "conduct clinical trials or supply human medicines" and insert "—

(i) carry out research relating to human medicines,
(ii) conduct clinical trials, or
(iii) manufacture or supply human medicines."

Member's explanatory statement
This amendment clarifies the meaning of Clause 1(3)(c).

Page 1, line 17, at end insert—

"(3A) Where regulations under subsection (1) may have an impact on the safety of human medicines, the appropriate authority may make the regulations only if the authority considers that the benefits of doing so outweigh the risks."

Member's explanatory statement
This amendment provides that the appropriate authority may make regulations that may have an impact on the safety of human medicines only if the authority considers that the benefits of doing so outweigh the risks.

Clause 2

LORD HUNT OF KINGS HEATH
BARONESS FINLAY OF LLANDAFF
BARONESS NORTHOVER
LORD BETHELL
LORD RIBEIRO

This amendment replaces an amendment tabled in the name of Lord Hunt of Kings Heath, published on daily sheet 154(a)

Page 2, line 32, at end insert ", or

(o) the use of tissues or cells (within the meanings given by regulation 5(1) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (S.I. 2007/1523)) in relation to human medicines."

Member's explanatory statement
This amendment would enable regulations under Clause 1(1) to make provision about the use of human tissues or cells in relation to human medicines.

Clause 7

LORD BETHELL

Page 4, line 36, after "a" insert "relevant"

Member's explanatory statement
This amendment and the amendment in the Minister's name to add a definition of "relevant person" to Clause 7 restrict the persons to whom information may be disclosed in reliance on Clause 7(2).

Page 5, line 8, at end insert—

"(4A) Nothing in this section authorises a disclosure of patient information without the consent of the individual to whom that information relates."

Member's explanatory statement
This amendment and the amendment in the Minister's name to add a definition of "patient information" to Clause 7 prevent Clause 7 authorising the disclosure of information from which patients can be identified without their consent.

Page 5, line 21, at end insert—

""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);"

Member's explanatory statement
See the explanatory statement for the amendment in the Minister's name adding a new subsection (4A) to Clause 7.

Page 5, line 24, at end insert—

""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."

Member's explanatory statement
See the explanatory statement to the first amendment to Clause 7 in the Minister's name.

Clause 9

LORD BETHELL

Page 6, line 22, leave out from beginning to "promote" on line 23 and insert "In making regulations under subsection (1), the appropriate authority's overarching objective must be to"

Member's explanatory statement
This amendment provides that the appropriate authority's overarching objective in making regulations under Clause 9 must be to promote one or more of the following: the health and welfare of animals; the health and safety of the public; the protection of the environment.

Page 6, line 27, leave out "they would" and insert "regulations under subsection (1) would contribute to this objective"

Member's explanatory statement
This amendment is consequential on the amendment to Clause 9(2) in the Minister's name.

Page 6, line 32, leave out "an attractive or" and insert "a"

Member's explanatory statement
This amendment omits the word "attractive" from Clause 9(3)(c).

Page 6, line 32, leave out "develop or supply veterinary medicines" and insert "—

(i) develop veterinary medicines, or

(ii) manufacture or supply veterinary medicines."

Member's explanatory statement
This amendment clarifies the meaning of Clause 9(3)(c).

Page 6, line 33, at end insert—

"(3A) Where regulations under subsection (1) may have an impact on the safety of veterinary medicines, the appropriate authority may make the regulations only if the authority considers that the benefits of doing so outweigh the risks."

Member's explanatory statement
This amendment provides that the appropriate authority may make regulations that may have an impact on the safety of veterinary medicines only if the authority considers that the benefits of doing so outweigh the risks.

Clause 12

LORD BETHELL

Page 8, line 19, after "a" insert "relevant"

Member's explanatory statement
This amendment and the other amendment to clause 12 in the Minister's name restrict the persons to whom information may be disclosed in reliance on Clause 12(2).

Page 9, line 6, at end insert—

""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."

Member's explanatory statement
See the explanatory statement to the other amendment to Clause 12 in the Minister's name.

Clause 14

LORD BETHELL

Page 9, line 33, leave out subsection (2) and insert—

"(2) In making regulations under subsection (1), the Secretary of State's overarching objective must be safeguarding public health."

Member's explanatory statement
This amendment provides that the Secretary of State's overarching objective in making regulations under Clause 14 must be safeguarding public health.

Page 9, line 35, leave out "they would" and insert "regulations under subsection (1) would contribute to this objective"

Member's explanatory statement
This amendment is consequential on the amendment in the Minister's name substituting Clause 14(2).

Page 9, line 39, leave out "an attractive or" and insert "a"

Member's explanatory statement
This amendment omits the word "attractive" from Clause 14(3)(c).

Page 9, line 40, leave out "develop or supply medical devices" and insert "—

(i) carry out research relating to medical devices,

(ii) develop medical devices, or

(iii) manufacture or supply medical devices."

Member's explanatory statement
This amendment clarifies the meaning of Clause 14(3)(c).

Page 9, line 40, at end insert—

"(4) Where regulations under subsection (1) may have an impact on the safety of medical devices, the Secretary of State may make the regulations only if the Secretary of State considers that the benefits of doing so outweigh the risks."

Member's explanatory statement
This amendment provides that the Secretary of State may make regulations that may have an impact on the safety of medical devices only if the Secretary of State considers that the benefits of doing so outweigh the risks.

After Clause 18

LORD BETHELL

Insert the following new Clause—

"Advisory committee

(1) The Secretary of State may by regulations establish, and make other provision about, a committee to advise the Secretary of State on such matters relating to medical devices as the regulations may specify.

(2) The regulations may (among other things) make provision about—
  (a) the membership of the committee;
  (b) the establishment by the committee of sub-committees;
  (c) matters to which the committee may, or must, have regard;
  (d) cooperation between the committee and the Commission on Human Medicines, and other bodies with expertise in relation to medical devices.

(3) The provision mentioned in subsection (2)(a) may include—
  (a) provision about the number of members, their appointment, and the circumstances in which a person ceases to be a member;
  (b) requirements as to the independence of members from the Secretary of State;
  (c) provision about the payment of remuneration and allowances to members."

Member's explanatory statement
This new Clause would enable regulations to be made creating a statutory committee to provide advice to the Secretary of State in relation to medical devices.

Clause 37

LORD BETHELL

Page 22, line 1, after "a" insert "relevant"

Member's explanatory statement
This amendment and the amendment to clause 37 in the Minister's name adding a definition of "relevant person" restrict the persons to whom information may be disclosed in reliance on Clause 37(5).

Page 22, line 3, at end insert—

"(5A) But subsection (5) does not authorise a disclosure of patient information without the consent of the individual to whom that information relates."

Member's explanatory statement
This amendment and the amendment in the Minister's name to add a definition of "patient information" to Clause 37 prevent Clause 37(5) authorising the disclosure of information from which patients can be identified without their consent.

Page 22, line 4, leave out "But"

Member's explanatory statement
This amendment is consequential on the amendment in the Minister's name adding a new subsection (5A) to Clause 37.

Page 22, leave out line 32

Member's explanatory statement
This amendment omits an unnecessary definition.

Page 22, line 32, at end insert—

""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);"

Member's explanatory statement
See the explanatory statement for the amendment in the Minister's name adding a new subsection (5A) to Clause 37.

Page 22, line 32, at end insert—

""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 medical devices in a country or territory outside the United Kingdom;

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

Member's explanatory statement
See the explanatory statement to the first amendment to Clause 37 in the Minister's name.

Clause 41

LORD BETHELL

Page 25, line 43, at end insert—

"(1) This section applies to regulations under a power in Part A1, 1, 2 or 3, apart from regulations under paragraph 9 of Schedule 1."

Member's explanatory statement
This amendment is consequential on the Minister's amendments to insert a new Part before Part 1 and a new Clause after Clause 18, and would enable regulations under powers in those provisions to make consequential and other connected provision.

Page 25, line 44, leave out "Regulations under sections 1(1), 9(1), 14(1) and 18(1)" and insert "The regulations"

Member's explanatory statement
See the explanatory statement for the other amendment to Clause 41 in the Minister's name.

Clause 43

LORD BETHELL

Page 26, line 13, after "Part" insert "A1,"

Member's explanatory statement
This amendment is consequential on the amendments in the Minister's name inserting a new Part relating to the Commissioner for Patient Safety. It requires the Secretary of State to carry out a public consultation before making regulations about the Commissioner.

Page 26, line 22, leave out "1(2) and (3), 9(2) and (3) or 14(2) and (3)" and insert "1, 9 or 14"

Member's explanatory statement
This amendment would require a consultation in relation to regulations under Clause 1, 9 or 14 to include a summary of the assessment of the person making the regulations of all matters mentioned in Clause 1, 9 or 14 (as the case may be), including new subsections (3A), (3A) and (4) inserted by amendments in the Minister's name into Clauses 1, 9 and 14 respectively (overall assessment of risk-benefit analysis).

Page 26, line 39, leave out from "to" to ", the" on line 40 and insert "any other regulations"

Member's explanatory statement
This amendment provides for the definition of "relevant authority" to apply in relation to regulations under new Part A1 (the Commissioner for Patient Safety) and the new Clause tabled in the Minister's name to appear after Clause 18 (advisory committee), as well as in relation to other regulations under Part 1, 2 or 3.

Clause 44

LORD BETHELL

Page 26, line 43, leave out "Secretary of State must lay before Parliament" and insert "relevant authority must lay before the appropriate legislature"

Member's explanatory statement
This amendment and the other amendments to Clause 44 in the Minister's name extend reporting obligations under Clause 44 so they apply in respect of regulations made by a Northern Ireland department and in respect of regulations under Clause 18.

Page 27, line 1, leave out "Secretary of State" and insert "relevant authority"

Member's explanatory statement
See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Page 27, line 1, leave out "and 14(1)" and insert ", 14(1) and 18(1)"

Member's explanatory statement
See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Page 27, line 3, leave out "Secretary of State" and insert "relevant authority"

Member's explanatory statement
See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Page 27, line 4, leave out "Secretary of State" and insert "relevant authority"

Member's explanatory statement
See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Page 27, line 8, leave out "Secretary of State's" and insert "relevant authority's"

Member's explanatory statement
See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Page 27, line 9, leave out "Secretary of State" and insert "relevant authority"

Member's explanatory statement
See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Page 27, line 10, leave out "or 14(1)" and insert ", 14(1) or 18(1)"

Member's explanatory statement
See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Page 27, line 13, leave out "or 14(1)" and insert ", 14(1) or 18(1)"

Member's explanatory statement
See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Page 27, line 14, at end insert—

"(5) In this section—

"appropriate legislature" means—

(a) in relation to a report of the Secretary of State, Parliament;

(b) in relation to a report of a Northern Ireland department, the Northern Ireland Assembly;

"relevant authority" means—

(a) in relation to regulations made under section 1(1) or 9(1) by the Secretary of State (whether acting alone or jointly with a Northern Ireland department), the Secretary of State;

(b) in relation to regulations made under section 1(1) or 9(1) by a Northern Ireland department (whether acting alone or jointly with the Secretary of State), the Northern Ireland department;

(c) in relation to regulations made under section 14(1) or 18(1), the Secretary of State."

Member's explanatory statement
See the explanatory statement for the first amendment to Clause 44 in the Minister's name.

Clause 45

LORD BETHELL

Page 27, line 16, after "Part" insert "A1,"

Member's explanatory statement
This amendment is consequential on the amendments in the Minister's name inserting a new Part relating to the Commissioner for Patient Safety.

Page 27, line 24, after "Part" insert "A1,"

Member's explanatory statement
This amendment is consequential on the amendments in the Minister's name inserting a new Part relating to the Commissioner for Patient Safety.

Page 28, line 12, after "Part" insert "A1,"

Member's explanatory statement
This amendment is consequential on the amendments in the Minister's name inserting a new Part relating to the Commissioner for Patient Safety. It provides for regulations about the Commissioner to be subject to the draft affirmative procedure.

Clause 47

LORD BETHELL

Page 30, line 2, at end insert—

"(ba) section 5(4),"

Member's explanatory statement
This amendment would commence the definition of "human medicines provision" from the day on which the Bill is passed.

Page 30, line 10, at end insert—

"(aa) Part A1."

Member's explanatory statement
This amendment is consequential on the amendments in the Minister's name inserting a new Part relating to the Commissioner for Patient Safety. It provides for those amendments to come into force two months after the Act is passed.

Page 30, line 14, leave out "section 18" and insert "Chapter 2 of Part 3"

Member's explanatory statement
This amendment is consequential on the Minister's amendment to insert a new clause after clause 18, in Chapter 2 of Part 3, and provides for the new clause to come into force two months after the Bill is passed.

Before Schedule 1

LORD BETHELL

Insert the following new Schedule—

"SCHEDULE A1

FURTHER PROVISION ABOUT THE COMMISSIONER FOR PATIENT SAFETY

Principles relating to core duties

1 (1) The Commissioner must prepare and publish a set of principles to govern the way in which the Commissioner will carry out the Commissioner's core duties.

(2) The Commissioner—

(a) may revise the principles, and

(b) must publish any revised version.

(3) The Commissioner must carry out a public consultation in preparing or revising the principles.

Involvement of patients

2 (1) The Commissioner must take reasonable steps to involve patients in the discharge of the Commissioner's core duties.

(2) The Commissioner must in particular take reasonable steps to—

(a) ensure that patients are aware of the Commissioner's core duties and of how they may communicate with the Commissioner, and

(b) consult patients, or persons who appear to the Commissioner to represent the interests of patients, on matters which the Commissioner proposes to consider in the discharge of the core duties.

Supplementary functions and information

3 (1) For the purposes of carrying out the core duties, the Commissioner may—

(a) make a report or recommendation to a relevant person;

Before Schedule 1 - *continued*

(b) consult or receive information from patients or any other person the Commissioner thinks appropriate;

(c) request information from a relevant person;

(d) share information with a relevant person.

(2) A relevant person to whom a report or recommendation is made under sub-paragraph (1)(a) must provide a response to that report or recommendation within such period as the Commissioner may reasonably require.

(3) A relevant person must, so far as reasonably practicable, comply with a request by the Commissioner to provide information within such period as the Commissioner may reasonably require.

(4) Nothing in this Schedule authorises a disclosure of information which contravenes the data protection legislation (but in determining whether a disclosure would do so, take into account the powers conferred by this Schedule).

(5) In this paragraph—

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

"health care" means all forms of health care provided for individuals, whether relating to physical or mental health, and including ancillary care;

"relevant person" means—

(a) a person who exercises functions of a public nature, relating to medicines or medical devices, so far as those functions are exercisable in relation to England;

(b) any other person who, in the course of providing health care, provides services relating to medicines or medical devices in relation to England.

Individual cases

4 (1) The Commissioner may not exercise functions in relation to an individual case.

(2) But sub-paragraph (1) does not prevent the Commissioner considering individual cases and drawing conclusions about them for the purpose of, or in the context of, considering a general issue.

Amendments to primary legislation

5 (1) In Part 1 of the Table at the end of paragraph 3 of Schedule 1 to the Public Records Act 1958 (definition of public records), at the appropriate place insert—

"Commissioner for Patient Safety."

(2) In Part 3 of Schedule 1 to the House of Commons Disqualification Act 1975 (offices disqualifying for membership), at the appropriate place insert—

"Commissioner for Patient Safety."

(3) In Part 6 of Schedule 1 to the Freedom of Information Act 2000 (other public bodies and offices: general), at the appropriate place insert—

"The Commissioner for Patient Safety."

Before Schedule 1 - *continued*

(4) In section 71 of the National Health Service Act 2006 (schemes for meeting losses and liabilities etc of certain health service bodies), in subsection (2), before paragraph (h) insert—

"(ga) the Commissioner for Patient Safety,".

(5) In Part 1 of Schedule 19 to the Equality Act 2010 (authorities subject to the public sector equality duty), in the group of entries under the heading "Health, social care and social security", at the appropriate place insert—

"The Commissioner for Patient Safety."

Regulations about appointment and operation

6 (1) The Secretary of State may by regulations make such provision as the Secretary of State considers appropriate with regard to the appointment and operation of the Commissioner.

(2) Regulations under sub-paragraph (1) may (among other things) contain provision for and about—

(a) the Commissioner's terms of office;

(b) remuneration or other benefits;

(c) the provision of financial or other assistance, including staff, accommodation, equipment or other facilities, for the Commissioner;

(d) requirements to prepare business plans;

(e) requirements to prepare reports;

(f) requirements to lay documents before Parliament;

(g) requirements to provide documents to the Secretary of State or other persons specified in the regulations;

(h) the conferring of functions on other persons in relation to the Commissioner;

(i) the appointment of a board to provide advice to the Commissioner."

Member's explanatory statement
This amendment makes further provision about the Commissioner for Patient Safety established by the amendment in the Minister's name to insert a new Part before Part 1.

In the Title

LORD BETHELL

Line 1, at beginning insert "Make provision about a Commissioner for Patient Safety in relation to human medicines and medical devices;"

Member's explanatory statement
This amendment would add a limb to the long title in relation to the new provisions tabled in the Minister's name for the purpose of establishing a Commissioner for Patient Safety.

Medicines and Medical Devices Bill

AMENDMENTS

TO BE MOVED

ON REPORT

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14 December 2020
