Medicines and Medical Devices Bill

MARSHALLED

LIST OF AMENDMENTS

TO BE MOVED

ON REPORT

The amendments have been marshalled in accordance with the Order of 6th January 2021, as follows –

Clauses 1 to 29	Schedule 2
Schedule 1	Clauses 40 to 49
Clauses 30 to 39	Title

[*Amendments marked ★ are new or have been altered*]

Amendment No.

Before Clause 1

LORD BETHELL

1 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

BARONESS THORNTON
LORD PATEL
BARONESS JOLLY

2 Page 1, line 8, at end insert "for a period of three years beginning with the day on which this Act is passed."

Member's explanatory statement
This amendment provides a sunset provision for Part 1 of the Bill requiring the Government to return with primary legislation. It is linked to the sunset amendments for Parts 2 and 3 of the Bill, and the amendments in the name of Lord Patel requiring consolidated legislation.

LORD SHARKEY
LORD JUDGE
BARONESS ANDREWS
LORD FORSYTH OF DRUMLEAN

3 Page 1, line 8, at end insert—

"( ) 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."

LORD BETHELL

4 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.

BARONESS THORNTON
BARONESS JOLLY
As an amendment to Amendment 4

5 Leave out "public health" and insert "the health and safety of the public"

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

LORD BETHELL

6 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).

BARONESS BENNETT OF MANOR CASTLE
BARONESS JOLLY

7 Page 1, line 14, at end insert—

"(ba) the protection of the environment;"

LORD BETHELL

8 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).

9 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).

BARONESS SHEEHAN
BARONESS BENNETT OF MANOR CASTLE
LORD ALTON OF LIVERPOOL
LORD CRISP

10 Page 1, line 17, at end insert—

"(d) the importance of prioritising the protection of human rights including citizens' right to access medicines as part of the right to the highest attainable standard of physical and mental health as stated in the International Covenant on Economic, Social and Cultural Rights of 1966;

(e) the public health safeguards within the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights which include but are not limited to the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted."

LORD BETHELL

11 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.

BARONESS THORNTON
As an amendment to Amendment 11

12 at end insert—

"(3B) Before making regulations under subsection (1) that may have an impact on the safety of human medicines, the Secretary of State must publish the criteria the appropriate authority will use to determine whether the benefits of laying regulations outweigh the risks.

(3C) Before making regulations in the circumstances referred to in subsection (3A), the appropriate authority must publish their assessment of why the benefits outweigh the risks."

Member's explanatory statement
This amendment requires the Secretary of State to publish the criteria that will be used by the appropriate authority to determine whether the benefits of regulations that may impact on the safety of human medicines outweigh the risk. It also requires the appropriate authority to publish their assessment of why benefits outweigh risks in these circumstances to allow for greater transparency and scrutiny.

Clause 2

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

13 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 3

LORD CLEMENT-JONES
BARONESS THORNTON

14★ Page 3, line 4, leave out "for any purpose to do with human medicines" and insert "for the purpose of ensuring patient safety"

Member's explanatory statement
This amendment would narrow the use of data in relation to falsified medicines to that which ensures patient safety.

After Clause 6

LORD FIELD OF BIRKENHEAD
BARONESS MEACHER
BARONESS WALMSLEY

15 Insert the following new Clause—

"Entitlement of a doctor to prescribe medicinal cannabis products

The appropriate authority must by regulations make provision to—

(a) grant authorisation to place on the market of the United Kingdom high quality, standardised medicinal cannabis products for prescription by a doctor (including, for the avoidance of doubt, by a general medical practitioner),

(b) permit doctors to prescribe medicinal cannabis products, and any device or article that is required in the administration of such products, and

(c) require the relevant regulatory and advisory bodies to obtain and evaluate relevant scientific and medical literature and data, including on long-term patients' experience in connection with cannabis for medicinal use (as well as the potential for such use) with particular reference to—

(i) the efficacy and therapeutic value of medicinal cannabis products,

(ii) matters pertaining to the safety of medicinal cannabis products, and

(iii) the medical conditions (indications) in respect of which medicinal cannabis products may be administered and used."

BARONESS THORNTON

16★ Insert the following new Clause—

"Strategy for tackling vaccination disinformation

(1) Within one month of the day on which this Act is passed, the Secretary of State must prepare and publish a strategy outlining plans to prevent the promotion of disinformation related to human vaccines.

(2) The overarching objective of the strategy must be safeguarding public health.

(3) The strategy must be laid before Parliament.

(4) In formulating the strategy under subsection (1), the Secretary of State must include proposals to—

(a) build public trust and encourage uptake of vaccines;

(b) require social media companies to promptly remove disinformation related to vaccines that has been reported to them by an appropriate authority, employees or other social media users, including financial and criminal penalties if they fail to act; and

(c) prohibit social media users or companies from directly profiting from vaccine disinformation through advertising revenue."

Member's explanatory statement
This amendment requires the Secretary of State to publish a strategy for tackling anti-vaccination disinformation within one month of the Bill passing.

Clause 7

LORD BETHELL

17 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).

BARONESS THORNTON
LORD PATEL
LORD CLEMENT-JONES

18★ Page 4, line 38, at end insert—

"( ) 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."

Member's explanatory statement
This amendment would allow a relevant authority to disclose information to a person outside the UK where required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of human medicine provided it is within the public interest to do so.

LORD BETHELL

19 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.

LORD CLEMENT-JONES
As an amendment to Amendment 19

20★ After the first "the" insert "informed"

Member's explanatory statement
This amendment would take the Government's amendment on patient consent further by ensuring the consent given in relation to identifiable information must be informed consent.

BARONESS THORNTON
As an amendment to Amendment 19

21 at end insert—

"(4B) In this section, "consent" means that an individual has given notice of their willingness for an appropriate authority to disclose patient information relating them."

Member's explanatory statement
This amendment ensures patient information can only be shared by an appropriate authority if the individual to whom it relates has given their explicit ("opt-in") consent.

LORD BETHELL

22 Page 5, line 14, at end insert—

"(5A) This section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law."

Member's explanatory statement
This amendment provides that Clause 7 does not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

23 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.

BARONESS THORNTON
As an amendment to Amendment 23

24 In paragraph (b), leave out "enables" and insert "could enable"

Member's explanatory statement
This amendment strengthens restrictions on the disclosure of information without patients consent to include data that could lead to the identification of individuals, owing to concerns that aggregate data could be subjected to de-identification or de-anonymisation practices.

LORD BETHELL

25 Page 5, line 24, at end insert—

""relevant person" means—
(a) the government of a country or territory outside the United Kingdom;

Clause 7 - *continued*

(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.

After Clause 7

LORD PATEL
BARONESS THORNTON
LORD KAKKAR
LORD MACKAY OF CLASHFERN

26 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."

Member's explanatory statement
This new Clause, and the other consolidation amendments in the name of Lord Patel, would require the Secretary of State to publish draft consolidated legislation within three years to streamline the existing regulatory framework. These amendments are linked to the amendment providing for a three year sunset provision in the name of Baroness Thornton.

Clause 9

BARONESS THORNTON
LORD PATEL
BARONESS JOLLY

27 Page 6, line 21, at end insert "for a period of three years beginning with the day on which this Act is passed."

Member's explanatory statement
This amendment provides a sunset provision for Part 2 of the Bill requiring the Government to return with primary legislation. It is linked to the sunset amendments for Parts 1 and 3 of the Bill, and the amendments in the name of Lord Patel requiring consolidated legislation.

LORD SHARKEY
LORD JUDGE
BARONESS ANDREWS
LORD FORSYTH OF DRUMLEAN

28 Page 6, line 21, at end insert—

"( ) 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."

LORD BETHELL

29 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.

30 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.

31 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).

32 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).

33 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.

BARONESS THORNTON
As an amendment to Amendment 33

34 at end insert—

"(3B) Before making regulations under subsection (1) that may have an impact on the safety of veterinary medicines, the Secretary of State must publish the criteria the appropriate authority will use to determine whether the benefits of laying regulations outweigh the risks.

(3C) Before making regulations in the circumstances referred to in subsection (3A), the appropriate authority must publish their assessment of why the benefits outweigh the risks."

Member's explanatory statement
This amendment requires the Secretary of State to publish the criteria that will be used by the appropriate authority to determine whether the benefits of regulations that may impact on the safety of veterinary medicines outweigh the risk. It also requires the appropriate authority to publish their assessment of why benefits outweigh risks in these circumstances to allow for greater transparency and scrutiny.

Clause 12

LORD BETHELL

35 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).

BARONESS THORNTON
LORD PATEL
LORD CLEMENT-JONES

36★ Page 8, line 21, at end insert—

"( ) 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."

Member's explanatory statement
This amendment would allow a relevant authority to disclose information to a person outside the UK where required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of human medicine provided it is within the public interest to do so.

LORD BETHELL

37 Page 8, line 39, at end insert—

"(5A) This section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law."

Member's explanatory statement
This amendment provides that Clause 12 does not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

38 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.

After Clause 12

LORD PATEL
BARONESS THORNTON
LORD KAKKAR

39 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."

Member's explanatory statement
This new Clause, and the other consolidation amendments in the name of Lord Patel, would require the Secretary of State to publish draft consolidated legislation within three years to streamline the existing regulatory framework. These amendments are linked to the amendment providing for a three year sunset provision in the name of Baroness Thornton.

Clause 14

BARONESS THORNTON
LORD PATEL
BARONESS JOLLY

40 Page 9, line 32, at end insert "for a period of three years beginning with the day on which this Act is passed"

Member's explanatory statement
This amendment provides a sunset provision for Part 3 of the Bill requiring the Government to return with primary legislation. It is linked to the sunset amendments for Parts 1 and 2 of the Bill, and the amendments in the name of Lord Patel requiring consolidated legislation.

LORD SHARKEY
LORD JUDGE
BARONESS ANDREWS
LORD FORSYTH OF DRUMLEAN

41 Page 9, line 32, at end insert—

"( ) 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."

LORD BETHELL

42 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.

43 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).

44 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).

45 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).

BARONESS FINLAY OF LLANDAFF
BARONESS MASHAM OF ILTON

46 Page 9, line 40, leave out "or" and insert "and"

Member's explanatory statement
This amendment is to ensure early access for NHS patients to medical devices and would allow monitoring of safety and efficacy in real time use.

LORD BETHELL

47 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.

BARONESS THORNTON
As an amendment to Amendment 47

48 at end insert—

"(5) Before making regulations under subsection (1) that may have an impact on the safety of medical devices, the Secretary of State must publish the criteria the appropriate authority will use to determine whether the benefits of laying regulations outweigh the risks.

(6) Before making regulations in the circumstances referred to in subsection (4), the appropriate authority must publish their assessment of why the benefits outweigh the risks."

Member's explanatory statement
This amendment requires the Secretary of State to publish the criteria that will be used by the appropriate authority to determine whether the benefits of regulations that may impact on the safety of medical devices outweigh the risks. It also requires the appropriate authority to publish their assessment of why benefits outweigh risks in these circumstances to allow for greater transparency and scrutiny.

Clause 18

LORD SHARKEY
LORD JUDGE
BARONESS ANDREWS
LORD FORSYTH OF DRUMLEAN

49 Page 11, line 40, at end insert—

"( ) 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."

After Clause 18

LORD BETHELL

50 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.

BARONESS THORNTON
As an amendment to Amendment 50

51 In subsection (1), leave out "may" and insert "must"

Member's explanatory statement
This would require the Secretary of State to make regulations to creating a statutory committee to provide advice in relation to medical devices.

As an amendment to Amendment 50

52 In subsection (2), leave out "may" and insert "must"

Member's explanatory statement
This would require the Secretary of State to make regulations to creating a statutory committee to provide advice in relation to medical devices.

As an amendment to Amendment 50

53 In subsection (3), leave out "may" and insert "must"

Member's explanatory statement
This would require the Secretary of State to make regulations to creating a statutory committee to provide advice in relation to medical devices.

Before Schedule 1

LORD BETHELL

54 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;

(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;

Before Schedule 1 - *continued*

"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."

(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;

Before Schedule 1 - *continued*

(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.

Clause 37

LORD BETHELL

55 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).

56 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.

BARONESS THORNTON
LORD PATEL
LORD CLEMENT-JONES

57★ Page 22, line 3, at end insert—

"( ) Where information is disclosed in accordance with subsection (5) 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."

Member's explanatory statement
This amendment would allow a relevant authority to disclose information to a person outside the UK where required for the purpose of giving effect to an international agreement or arrangement concerning the regulation of human medicine provided it is within the public interest to do so.

LORD BETHELL

58 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.

59 Page 22, line 27, at end insert—

"(9A) This section does not limit the circumstances in which information may be disclosed under any other enactment or rule of law."

Member's explanatory statement
This amendment provides that Clause 37 does not limit the circumstances in which information may be disclosed under any other enactment or rule of law.

60 Page 22, leave out line 32

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

61 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.

62 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.

After Clause 39

LORD PATEL
BARONESS THORNTON
LORD KAKKAR
BARONESS JOLLY

63 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."

Member's explanatory statement
This new Clause, and the other consolidation amendments in the name of Lord Patel, would require the Secretary of State to publish draft consolidated legislation within three years to streamline the existing regulatory framework. These amendments are linked to the amendment providing for a three year sunset provision in the name of Baroness Thornton.

Schedule 2

LORD BETHELL

64 Page 39, line 39, at end insert—

"(2A) In respect of an offence under this regulation—

(a) a magistrates' court in England and Wales may try an information laid before the earlier of—

(i) the end of the period of one year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(ii) the end of the period of three years beginning with the day on which the offence was committed;

(b) a magistrates' court in Northern Ireland may hear and determine any complaint made before the earlier of—

(i) the end of the period of one year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(ii) the end of the period of three years beginning with the day on which the offence was committed;

(c) in Scotland, summary proceedings for the offence may be commenced before the earlier of—

(i) the end of the period of one year beginning with the day on which evidence which the prosecutor thinks is sufficient to justify a prosecution comes to the knowledge of the prosecutor, and

(ii) the end of the period of three years beginning with the day on which the offence was committed.

(2B) For the purposes of paragraph (2A)(a)(i), (b)(i) and (c)(i)—

Schedule 2 - *continued*

(a) a certificate signed by or on behalf of the prosecutor and stating the date on which such evidence came to the prosecutor's knowledge is conclusive evidence of that fact, and
(b) a certificate stating that matter and purporting to be so signed is to be treated as so signed until the contrary is proved."

Member's explanatory statement
This amendment ensures that prosecutions for an offence under new regulation 60A of the Medical Devices Regulations 2002 can be brought before the earlier of one year from the prosecutor thinking there was sufficient evidence to justify a prosecution or three years of the commission of the offence, as is currently the case with regard to equivalent offences under section 12 of the Consumer Protection Act 1987.

After Clause 40

BARONESS CUMBERLEGE
LORD PATEL
LORD HUNT OF KINGS HEATH
BARONESS JOLLY

65 Insert the following new Clause—

"Independent Patient Safety Commissioner

(1) An independent Patient Safety Commissioner is established.

(2) The Office of Patient Safety is to be hosted and funded by the Cabinet Office.

(3) The Patient Safety Commissioner must publish a business plan, reviewed annually, which sets out, in relation to the discharge of the Commissioner's functions—

(a) the Commissioner's proposed main activities for the period covered by the plan (including the matters he or she intends to consider or investigate), and

(b) the Commissioner's proposed strategic priorities for that period.

(4) The Patient Safety Commissioner must appoint an advisory board to provide the Commissioner with advice and assistance relating to the discharge of his or her functions, consisting of persons who (taken together) represent a broad range of interests which are relevant to the Patient Safety Commissioner's functions, and must from time to time publish a report on the procedure followed and the criteria used when making appointments to the advisory board.

(5) The Commissioner's functions are to—

(a) promote and improve patient safety with respect to the use of medicines and medical devices;

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

(c) make recommendations to the Secretary of State;

(d) establish and, when deemed appropriate, revise the Principles of Better Patient Safety;

After Clause 40 - *continued*

(e) receive direct reports from patients and other members of the public, any other persons (whether natural or corporate), and the Secretary of State and, when the Commissioner deems appropriate, share those reports with relevant organisations and the Secretary of State;

(f) produce and lay before Parliament for the attention of any committees of either House whose remit covers medicines and medical devices—

(i) an Annual Report and Accounts, and

(ii) any other reports regarding patient safety, which may include recommendations to improve patient safety with respect to the use of medicines and medical devices.

(6) For the purposes of subsection (5)(d), the Principles of Better Patient Safety must—

(a) describe expected patient safety outcomes relating to the safety of medicines and medical devices; and

(b) be drafted in consultation with the public.

(7) For the purposes of subsection (5)(f), the Commissioner may require a public body and other persons (whether natural or corporate) to provide such information as is reasonable in order to fulfil that function relating to the safety of medicines and medical devices.

(8) In fulfilling his or her functions, the Commissioner may do anything which appears to be necessary or expedient for the purpose of, or in connection with, the performance of his or her functions.

(9) The Commissioner has the duty to involve and inform patients and other members of the public in carrying out his or her functions.

(10) The Commissioner may make recommendations to the Minister for the Cabinet Office for any additional powers which the Commissioner considers may be necessary to fulfil the duties and functions under this section.

(11) The Minister for the Cabinet Office may by regulations make any other provision relating to the establishment of the Commissioner, including—

(a) the appointment of a Commissioner,

(b) the terms of office,

(c) remuneration and financial and other assistance,

(d) staff, and

(e) any other matters the Minister for the Cabinet Office considers appropriate.

(12) A statutory instrument containing regulations under this section may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament."

Member's explanatory statement

This new Clause would establish the Patient Safety Commissioner on a statutory basis, as recommended in the report of the Independent Medicines and Medical Devices Safety Review.

LORD HUNT OF KINGS HEATH

66 Insert the following new Clause—

"Availability of medicines and medical devices for human use on the National Health Service

(1) The National Institute for Health and Care Excellence must have regard to the need—

(a) to address the implications of health inequalities when assessing the cost effectiveness of medicines and medical devices,

(b) to support early patient access to effective new medicines and medical devices, including by accepting a greater degree of uncertainty and risk in recommending their use,

(c) to ensure patients with rare diseases have access to medicines and medical devices that they need, and

(d) to support the use of curative therapies involving medicines and medical devices.

(2) The Secretary of State must lay a report and impact assessment before both Houses of Parliament setting out how the National Institute for Health and Care Excellence has implemented its duty under subsection (1), in particular in its manual on process and methods for developing NICE guidelines."

Member's explanatory statement
This new Clause would require the National Institute for Health and Care Excellence to ensure that its recommendations support the NHS in the ways described in subsection (1).

LORD HUNT OF KINGS HEATH
BARONESS CUMBERLEGE
BARONESS BENNETT OF MANOR CASTLE

67 Insert the following new Clause—

"Medicines and Medical Devices Redress Agency

The Secretary of State must, by the end of the period of 12 months beginning with the day on which this Act is passed, bring proposals before Parliament to establish a Redress Agency for those harmed by medicines and medical devices."

BARONESS CUMBERLEGE
BARONESS BENNETT OF MANOR CASTLE
LORD O'SHAUGHNESSY
LORD HUNT OF KINGS HEATH

68 Insert the following new Clause—

"Redress schemes

The Secretary of State must, by the end of the period of three months beginning with the day on which this Act is passed, bring proposals before Parliament to establish redress schemes for those avoidably harmed by—

(a) hormone pregnancy tests,

(b) sodium valproate, and

(c) pelvic mesh."

Member's explanatory statement
This new Clause would require the Secretary of State to create redress schemes for those who have already suffered avoidable harm related to the medicines and medical devices specified in the new Clause, and would thus implement one of the recommendations made in the report of the Independent Medicines and Medical Devices Safety Review.

BARONESS THORNTON
LORD PATEL

69 Insert the following new Clause—

"Northern Ireland and regulatory divergence

(1) The Secretary of State must make an annual report to Parliament on areas of regulatory divergence between Northern Ireland and the rest of the United Kingdom in matters covered by this Act.

(2) Where the Secretary of State has identified areas of potential regulatory divergence between Northern Ireland and the rest of the United Kingdom, the Secretary of State must set out plans to mitigate the adverse effects of such divergence in the annual report."

Member's explanatory statement
This new Clause would require the Secretary of State to report on regulatory divergence between Northern Ireland and the rest of the UK.

Clause 41

LORD BETHELL

70 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.

71 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

72 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.

73 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).

74 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

75 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.

76 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.

77 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.

BARONESS THORNTON
BARONESS JOLLY

78 Page 27, line 3, leave out subsection (2) and insert—

"(2) In preparing a report, the relevant authority must consult—

(a) relevant patient groups,
(b) healthcare professionals,
(c) veterinary professionals,
(d) healthcare providers,
(e) pharmaceutical and pharmacy organisations,

Clause 44 - *continued*

(f) medical research organisations,
(g) relevant regulators, and
(h) anyone else whom the Secretary of State considers appropriate."

Member's explanatory statement
This amendment requires the relevant authority to consult patient, healthcare and industry stakeholders when preparing a report.

LORD BETHELL

79 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.

80 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.

81 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.

82 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.

83 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.

84 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.

85 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—

Clause 44 - *continued*

(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

86 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.

87 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.

LORD SHARKEY
LORD JUDGE
BARONESS ANDREWS
LORD FORSYTH OF DRUMLEAN

88 Page 27, line 39, column 2, leave out paragraph (b)

89 Page 28, line 10, column 2, leave out paragraph (b)

90 Page 28, leave out line 12

LORD BETHELL

91 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.

After Clause 45

LORD SHARKEY
LORD JUDGE
BARONESS ANDREWS
LORD FORSYTH OF DRUMLEAN

92 Insert the following new Clause—

"Super-affirmative procedure

(1) For the purposes of section 1(1), section 9(1), section 14(1) and section 18(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."

After Clause 45 - *continued*

93 Insert the following new Clause—

"Super-affirmative procedure: Northern Ireland

(1) For the purposes of section 1(1), section 9(1), section 14(1) and section 18(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 (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 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."

Clause 47

LORD BETHELL

94 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.

95 Page 30, line 10, at end insert—

"(za) 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.

96 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.

In the Title

LORD BETHELL

97 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

MARSHALLED
LIST OF AMENDMENTS
TO BE MOVED
ON REPORT

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7 January 2021
