LORDS AMENDMENTS TO THE

MEDICINES AND MEDICAL DEVICES BILL

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

Before Clause 1

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."

Clause 1

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

3 Page 1, line 6, at end insert—

"(1A) Regulations made under subsection (1) that introduce significant new policy or significant changes to existing policy are subject, in relation to regulations made by the Secretary of State, to the super-affirmative procedure set out in section (*Super-affirmative procedure*), in relation to regulations made by a Northern Ireland department, to section (*Super-affirmative procedure: Northern Ireland*), and, in relation to regulations of the Secretary of State and a Northern Ireland department acting jointly, to both."

4 Page 1, line 6, at end insert—

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

5 Page 1, line 7, leave out "making regulations under subsection (1)" and insert "considering whether regulations under subsection (1) would contribute to this objective"

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

"(c) the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to—

(i) carry out research relating to human medicines,

(ii) conduct clinical trials, or

(iii) manufacture or supply human medicines."

7 Page 1, line 12, at end insert—

"(2A) 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."

Clause 2

8 Page 2, line 23, 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."

Clause 5

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

10 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."

After Clause 6

11 Insert the following new Clause—

"Disclosure of information in accordance with international agreements

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

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

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

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

(b) it is in the public interest.

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

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

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

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

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

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

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

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

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

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

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

(9) In this section—

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

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

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

(a) relates to—

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

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

(iii) an individual's care or treatment,

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

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

"relevant authority" means—

(a) the Secretary of State, or

(b) the Department of Health in Northern Ireland;

"relevant person" means—

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

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

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

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

12 Insert the following new Clause—

"Requirement for draft consolidated legislation: human medicines

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

Clause 8

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

14 Page 5, line 12, at end insert—

"(1A) Regulations made under subsection (1) that introduce significant new policy or significant changes to existing policy are subject, in relation to regulations made by the Secretary of State, to the super-affirmative procedure set out in section (*Super-affirmative procedure*), in relation to regulations made by a Northern Ireland department, to section (*Super-affirmative procedure: Northern Ireland*), and, in relation to regulations of the Secretary of State and a Northern Ireland department acting jointly, to both."

15 Page 5, line 12, at end insert—

"(1B) In making regulations under subsection (1), the appropriate authority's overarching objective must be to 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."

16 Page 5, line 13, leave out "making regulations under subsection (1)" and insert "considering whether regulations under subsection (1) would contribute to this objective"

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

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

"(c) the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to—

(i) develop veterinary medicines, or

(ii) manufacture or supply veterinary medicines."

19 Page 5, line 19, at end insert—

"(2A) 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."

Clause 10

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

21 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."

After Clause 10

22 Insert the following new Clause—

"Disclosure of information in accordance with international agreements

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

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

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

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

(b) it is in the public interest.

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

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

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

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

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

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

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

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

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

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

(8) In this section—

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

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

"relevant authority" means—

(a) the Secretary of State, or

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

"relevant person" means—

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

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

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

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

23 Insert the following new Clause—

"Requirement for draft consolidated legislation: veterinary medicines

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

Clause 12

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

25 Page 7, line 22, at end insert—

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

26 Page 7, line 22, at end insert—

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

27 Page 7, line 23, leave out "making regulations under subsection (1)" and insert "considering whether regulations under subsection (1) would contribute to this objective"

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

"(c) the likelihood of the United Kingdom being seen as a favourable place in which to—

(i) carry out research relating to medical devices,

(ii) develop medical devices, or

(iii) manufacture or supply medical devices."

29 Page 7, line 28, at end insert—

"(3) 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."

Clause 16

30 Page 9, line 27, at end insert—

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

After Clause 16

31 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."

Clause 35

32 Page 19, line 33, at end insert—

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

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

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

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

(b) it is in the public interest."

33 Page 19, line 34, leave out "But"

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

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

36 Page 20, line 18, at end insert—

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

37 Page 20, line 22, 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);"

38 Page 20, line 22, 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."

39 Page 20, leave out line 23

After Clause 37

40 Insert the following new Clause—

"Requirement for draft consolidated legislation: medical devices

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

Clause 39

41 Page 23, line 36, 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."

42 Page 23, line 37, leave out "Regulations under sections 1(1), 8(1), 12(1) and 16(1)" and insert "The regulations"

Clause 41

43 Page 24, line 8, after "Part" insert "A1,"

44 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.

(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, 8 or 12 (as the case may be)."

45 Page 24, line 25, leave out from "to" to ", the" in line 26 and insert "any other regulations"

After Clause 41

46 Insert the following new Clause—

"Reporting requirements

(1) As soon as reasonably practicable after the end of each reporting period, the relevant authority must lay before the appropriate legislature a report on the operation of any regulations made by the relevant authority under sections 1(1), 8(1), 12(1) and 16(1) that were in force at any time during the reporting period.

(2) In preparing a report, the relevant authority must consult such persons as the relevant authority 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 relevant authority's response to those concerns or proposals, including any plan the relevant authority may have to make further regulations under section 1(1), 8(1), 12(1) or 16(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), 12(1) or 16(1) comes into force, and

(b) each successive period of 24 months.

(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 8(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 8(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 12(1) or 16(1), the Secretary of State."

Clause 42

47 Page 24, line 28, after "Part" insert "A1,"

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

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

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

If the regulations contain provision made in reliance on	*the regulations are subject to*
section 15	the made affirmative procedure, where the regulations contain a declaration that the Secretary of State considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health

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

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

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

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

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

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

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

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

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

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

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

(i) each House of Parliament, and

(ii) the Northern Ireland Assembly.

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

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

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

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

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

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

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

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

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

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

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

(a) Parliament is dissolved or prorogued, or

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

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

(a) dissolved,

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

(c) adjourned for more than 6 days.

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

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

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

After Clause 42

49 Insert the following new Clause—

"Super-affirmative procedure

(1) For the purposes of section 1(1), section 8(1), section 12(1) and section 16(1), the "super-affirmative procedure" is as follows.

(2) The Secretary of State must lay before Parliament—

(a) a draft of the regulations, and

(b) a document which explains the draft regulations.

(3) Where a draft of the regulations is laid before Parliament under subsection (2), no statutory instrument containing the regulations is to be laid before Parliament until after the expiry of the 30-day period.

(4) The Secretary of State must request a committee of either House whose remit includes health, science or technology to report on the draft regulations within the 30-day period.

(5) In preparing a draft statutory instrument containing the regulations, the Secretary of State must take account of—

(a) any representations,

(b) any resolution of either House of Parliament, and

(c) any recommendations of a committee under subsection (4), made within the 30-day period with regard to the draft regulations.

(6) If, after the 30-day period, the Secretary of State wishes to make regulations in the terms of the draft or a revised draft, he or she must lay before Parliament a statement—

(a) stating whether any representations, resolutions or recommendations were made under subsection (5);

(b) giving details of any representations, resolutions or recommendations so made; and

(c) explaining any changes made in any revised draft of the regulations.

(7) The Secretary of State may make a statutory instrument containing the regulations (whether or not revised) if, after the laying of the statement required under subsection (6), a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

(8) In this section, reference to "the 30-day period" in relation to any draft regulations is to the period of 30 days beginning with the day on which the original draft regulations were laid before Parliament.

(9) For the purposes of subsection (8) no account is to be taken of any time during which Parliament is dissolved or prorogued or during which either House is adjourned for more than four days."

50 Insert the following new Clause—

"Super-affirmative procedure: Northern Ireland

(1) For the purposes of section 1(1) and section 8(1), the "super-affirmative resolution procedure" in the Northern Ireland Assembly is as follows.

(2) The Department must request a committee of the Assembly whose remit includes health, science or technology to report on the draft regulations within the 30-day period.

(3) A Northern Ireland Department must take account of—

(a) any representations,

(b) any resolution of the Assembly, and

(c) any recommendations of a committee under subsection (2), made within the 30-day period.

(4) If, after the 30-day period, the Department wishes to make regulations in the terms of the draft, it must lay before the Assembly a statement—

(a) stating whether any representations were made under subsection (3)(a); and

(b) if any representations were so made, giving details of them.

(5) The Department may after the laying of such a statement lay before the Assembly for approval by affirmative resolution the draft regulations in their original form, or revised draft regulations together with an explanation of the changes made.

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

(7) For the purposes of subsection (6) no account is to be taken of any time during which the Assembly is dissolved or adjourned for more than four days."

Clause 44

51 Page 26, line 2, at end insert—

"(ba) section 5(3),"

52 Page 26, line 10, at end insert—

"(za) Part A1,"

53 Page 26, line 14, leave out "section 16" and insert "Chapter 2 of Part 3"

Before Schedule 1

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;

"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;
(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."

Schedule 2

55 Page 35, 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)—

(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."

In the Title

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

LORDS AMENDMENTS TO THE
Medicines and Medical Devices Bill

Ordered, by The House of Commons,
to be Printed pursuant to Standing Order
Nos. 78 and 57A, 21*st January* 2021.