Medicines and Medical Devices Bill

SIXTH

MARSHALLED

LIST OF AMENDMENTS

TO BE MOVED

IN GRAND COMMITTEE

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

Amendment No.

Clause 16

BARONESS FINLAY OF LLANDAFF

95 Page 9, line 18, leave out "may" and insert "must"

Member's explanatory statement
This amendment is designed to seek assurances from the Minister that the Government will proceed to make regulations under the Bill, setting up the new information system envisaged by Clause 16.

BARONESS THORNTON

96 Page 9, line 22, after "of" insert "all"

Member's explanatory statement
This is a probing amendment seeking clarity about whether the Government intends to track all medical devices used in the UK, rather than a selection.

LORD KAKKAR
LORD PATEL

97 Page 9, line 27, at end insert—

"(d) provisional licences granted for new devices before they are placed on the market to inform the decision whether to grant final marketing authorisation under a full licence."

Member's explanatory statement
The purpose of this amendment is to extend the reach of Clause 16 to include provision for the establishment of an information system for assessing the safety and performance of medical devices before they are placed on the market, via a provisional licence.

LORD SHARKEY
LORD FORSYTH OF DRUMLEAN
BARONESS ANDREWS

98 Page 9, line 27, at end insert—

"( ) Regulations made under subsection (1) 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."

Member's explanatory statement
This amendment, and the amendments to page 1, line 6, page 5 line 12 and page 7 line 22 in the name of Lord Sharkey, replace the existing affirmative procedure with a super-affirmative procedure in order to increase parliamentary scrutiny.

BARONESS FINLAY OF LLANDAFF
LORD RIBEIRO

99 Page 9, line 28, leave out "may" and insert "must"

Member's explanatory statement
This amendment seeks to make the list of specified issues for the regulations to cover mandatory.

BARONESS FINLAY OF LLANDAFF
LORD RIBEIRO
BARONESS JOLLY

100 Page 9, line 37, at end insert—

"( ) requiring that, subject to patient consent, information about any medical device implanted in the human body is entered and retained in an information system established under subsection (1);

( ) requiring that, subject to patient consent, information about the use of other medical devices as may be necessary for the protection of patient safety is entered and retained in an information system established under subsection (1);

( ) requiring that information systems established under subsection (1) are subject to expert oversight;

( ) establishing a mechanism for patients to enter reports of their experience following the use of any medical device in their treatment, requiring that this information be retained in any relevant information system established under subsection (1)."

BARONESS FINLAY OF LLANDAFF
BARONESS BENNETT OF MANOR CASTLE

101 Page 9, line 37, at end insert—

"( ) establishing a mechanism for patients to enter reports of their experience following the use of any medical device in their treatment, to be retained in any relevant information system established under subsection (1)."

Member's explanatory statement
The amendment requires that patients should have a direct route to report their experience into any information system established under this section.

BARONESS FINLAY OF LLANDAFF

101A★ Page 9, line 37, at end insert—

"( ) specifying how the work of the Information Centre will be overseen by the devolved administrations (or agencies accountable to them) in Scotland, Wales and Northern Ireland."

BARONESS FINLAY OF LLANDAFF
LORD RIBEIRO

102 Page 10, line 20, leave out "may" and insert "must"

Member's explanatory statement
This amendment seeks to strengthen the provisions of this Clause in relation to unique identifiers on medical devices, mandating, rather than permitting, their inclusion in the registration system set up by Clause 16.

BARONESS CUMBERLEGE

103 Page 10, line 41, at end insert—

"( ) The Secretary of State must by regulations set out the categories or types of information held by the Information Centre or other persons that are subject to the consent of the patient to whom the information relates."

Member's explanatory statement
The purpose of this amendment is to clarify which information held by the healthcare system requires the consent of the patient to whom it relates.

LORD LANSLEY
LORD WOOLF
BARONESS FINLAY OF LLANDAFF

104 Page 10, line 42, at end insert—

"( ) In making regulations under subsection (1), and in the use of information provided by virtue of this section, the Secretary of State must have regard to the Caldicott principles, as set out in the Report on the Review of Patient-Identifiable Information, published in 1997, and the Information Governance Review, published in 2013."

Member's explanatory statement
This amendment would require regulations under this section to have regard to the Caldicott principles.

After Clause 16

BARONESS THORNTON
BARONESS BENNETT OF MANOR CASTLE

105 Insert the following new Clause—

"Requirement for consultation with devolved authorities

(1) Before making regulations under section 16 that contain provision which is within the legislative competence of a devolved legislature, the Secretary of State must consult the relevant devolved authority on that provision and have regard to the views of that devolved authority.

(2) In this section—

"devolved authority" means the Scottish Ministers, the Welsh Ministers, Northern Ireland ministers or a Northern Ireland department; and

"devolved legislature" means the Scottish Parliament, Senedd Cymru or the Northern Ireland Assembly.

(3) A provision is within the legislative competence of a devolved legislature if—

(a) it would be within the legislative competence of the Scottish Parliament if it were contained in an Act of the Scottish Parliament;

(b) it would be within the legislative competence of Senedd Cymru if it were contained in an Act of Senedd Cymru (including any provision that could only be made with the consent of a Minister of the Crown); or

(c) the provision, if it were contained in an Act of the Northern Ireland Assembly—

(i) would be within the legislative competence of the Assembly, and

(ii) would not require the consent of the Secretary of State."

Member's explanatory statement
This new Clause would require the Secretary of State to consult the devolved administrations before making regulations concerning UK-wide information systems.

BARONESS THORNTON

106 Insert the following new Clause—

"Annual report on Medical Devices Information Systems

(1) The Secretary of State must, by the end of the period of 12 months beginning with the day on which this Act is passed, and every year thereafter, lay before Parliament a report on the operation of any information systems established by the Information Centre under the powers conferred by section 16 of this Act.

(2) The annual report laid under subsection (1) must include, but is not limited to—

(a) the number of patients who receive or are treated with a medical device, or into whom a medical device is implanted;

(b) any safety concerns received; and

(c) any regulatory action taken.

(3) The Secretary of State must provide a copy of every report laid before Parliament under this paragraph—

After Clause 16 - *continued*

(a) to the Scottish Ministers,
(b) to the Welsh Ministers, and
(c) to the Northern Ireland Ministers or the relevant Northern Ireland department."

Member's explanatory statement
This new Clause would require the Secretary of State to prepare a report about Medical Device registers operated by NHS Digital, lay it before Parliament and send it to the devolved administrations.

BARONESS JOLLY
BARONESS BARKER
BARONESS BURT OF SOLIHULL
BARONESS FINLAY OF LLANDAFF

107 Insert the following new Clause—

"Introduction of registries for patient safety

(1) Within 6 months of this Act coming into force, the Secretary of State must by regulations introduce provisions enabling the creation of a registry of patients who have undergone a procedure to insert surgical mesh.

(2) The purpose of the registry under subsection (1) is to research and audit the outcomes of such surgeries in terms of the device safety and patient reported outcomes measures.

(3) When creating the registry under subsection (1) the Government must consult—
(a) relevant patient groups;
(b) healthcare professionals; and
(c) anyone else whom the Secretary of State considers appropriate.

(4) Accompanying the regulations the Secretary of State must also lay before Parliament a report outlining the progress towards the establishment of a comprehensive national database of patients who have undergone a procedure involving the insertion of a medical device or implant, and how the database may feed into the creation of further registries.

(5) 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."

Clause 35

LORD PATEL
LORD MACKAY OF CLASHFERN
BARONESS CUMBERLEGE

108 Page 19, line 22, at end insert—

"( ) The Secretary of State must disclose information for the purpose of warning the public about concerns relating to a medical device where there is a clear threat to public safety."

Member's explanatory statement
This amendment places a duty on the Secretary of State to disclose the information where there is a clear threat to public safety.

LORD BETHELL

109 Page 19, line 33, at end insert—

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

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

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

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

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

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

Clause 37

LORD FREYBERG
LORD CLEMENT-JONES

112 Page 21, line 46, leave out "(7)" and insert "(8)"

113 Page 22, line 2, at end insert—

"( ) In regulation 2 (interpretation), in paragraph (1) in the definition of "medical device", after "software" insert "and algorithms including methodologies for the interpretation of data, and associated technical architecture,"."

Member's explanatory statement
This amendment updates the definition of medical device to bring it in line with the EU and US regulation, acknowledging the progress of technology beyond the Medical Devices Regulations 2002.

LORD PATEL
LORD MACKAY OF CLASHFERN

114 Page 22, line 3, leave out subsection (5)

Member's explanatory statement
This amendment means Regulation 3B remains in place.

After Clause 37

LORD PATEL
LORD KAKKAR

115 Insert the following new Clause—

"Requirement for consolidated legislation: medical devices

The Secretary of State must publish draft legislation consolidating existing legislation as it applies to medical devices within three years after the day on which this Act is passed."

Member's explanatory statement
This new Clause would commit the Secretary of State to introducing new, streamlined legislation within three years.

BARONESS THORNTON

116 Insert the following new Clause—

"Requirement for draft consolidated legislation

The Secretary of State must, within the period of two 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 would require the Secretary of State to publish draft consolidated legislation within two years to streamline the existing regulatory framework.

After Clause 38

BARONESS CUMBERLEGE
LORD PATEL
LORD HUNT OF KINGS HEATH
BARONESS JOLLY

117 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.

After Clause 38 - *continued*

(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 Principles of Better Patient Safety;

(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,

After Clause 38 - *continued*

(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.

BARONESS THORNTON

118 Insert the following new Clause—

"International trade agreements

(1) Regulations under section 1(1), section 8(1) and section 12(1) may make provision for the purpose of implementing an international trade agreement, subject to the provisions of subsection (2).

(2) No provision can be made for the purpose of implementing an international trade agreement if the provision would in any way undermine or restrict the ability of an appropriate authority—
(a) to regulate and maintain the quality and safety of medicines and medical devices;
(b) to regulate and control the pricing and reimbursement systems for the purchase of medicines and medical devices; or
(c) to regulate and maintain the level of protection afforded in relation to information and patients' data collected for the purpose of a register of medical devices."

Member's explanatory statement
This new Clause would protect medicines and medical devices regulations from any form of control from outside the UK in the event of a trade deal.

BARONESS THORNTON
BARONESS RITCHIE OF DOWNPATRICK

119 Insert the following new Clause—

"Northern Ireland and regulatory divergence

(1) The Secretary of State must work together with the appropriate authority in Northern Ireland to minimise the potential for and mitigate against regulatory divergence in relation to human medicines, veterinary medicines and medical devices.

After Clause 38 - *continued*

(2) Where the Secretary of State has identified areas of regulatory divergence in relation to human medicines, veterinary medicines and medical devices between Northern Ireland and the rest of the UK, the Secretary of State must lay a report before both Houses of Parliament setting out how the divergence will impact—

(a) the UK; and

(b) Northern Ireland.

(3) The report must set out the steps the appropriate authorities have taken to mitigate against such divergence."

Member's explanatory statement

This Clause would require the Secretary of State to work with the appropriate authority in Northern Ireland to minimise the potential for regulatory divergence relating to medicines and devices, and report any areas of regulatory divergence to Parliament, including the impact they will have, and report on actions to mitigate against adverse consequences arising from divergence.

LORD PATEL
LORD MACKAY OF CLASHFERN

120 Insert the following new Clause—

"Northern Ireland and regulatory divergence

(1) The Secretary of State must make an annual report to Parliament on potential 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.

BARONESS CUMBERLEGE
LORD HUNT OF KINGS HEATH
BARONESS RITCHIE OF DOWNPATRICK

121 Insert the following new Clause—

"Independent medicines and medical devices safety review: task force for implementation

(1) Within three months of this Act being passed, the Secretary of State must appoint an independent task force.

(2) The task force must—

(a) have an independent Chair;

(b) be accountable to an oversight governance board; and

(c) include representatives of the Independent Medicines and Medical Devices Safety Review, published on 8 July 2020.

After Clause 38 - *continued*

(3) The task force's functions are—

(a) to deliver a timeline for the implementation in full of the recommendations of the Review in subsection (2)(c); and

(b) to implement the recommendations of the Review in subsection (2)(c).

(4) Once the task force has fulfilled the functions in subsection (3), it will cease to exist."

Member's explanatory statement
This new clause would establish the task force whose role it would be to implement recommendations set out in the report of the Independent Medicines and Medical Devices Safety Review.

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

122 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

123 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.

LORD HUNT OF KINGS HEATH

124 Insert the following new Clause—

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

(1) The Secretary of State must require the National Institute for Health and Care Excellence to ensure that it takes account of the need for improved availability of innovative medicines and medical devices for human use on the National Health Service.

(2) The Secretary of State must lay a report and impact assessment before both Houses of Parliament setting out how the implementation of the National Institute for Health and Care Excellence processes and methods programme manual will help to improve the availability of innovative medicines and medical devices for human use within the National Health Service.

(3) The report in subsection (2) must set out the anticipated impact of the changes contained within the new programme manual on inward investment and the attractiveness of the UK life sciences sector for the development of medicines and medical devices."

Member's explanatory statement
This new Clause would require the Secretary of State to work with the National Institute for Health and Care Excellence to ensure that the latest medicines for human use are able to reach patients on the National Health Service.

BARONESS JOLLY

125 Insert the following new Clause—

"Future regulatory alignment

(1) The appropriate authority must ensure that the provisions of regulations under section 1(1) and section 12(1) align as much as reasonably practicable with the relevant law of the European Union.

(2) The Government must seek full membership of—

(a) the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; and

(b) any other organisation the Government, in consultation with relevant industry bodies, believes will improve regulatory alignment with the European Union and standards in medicines and medical devices in the UK."

Member's explanatory statement
This new Clause is intended to probe the Government's intentions for future regulatory alignment with the European Union, and the UK's relationships with relevant international organisations following our exit from the European Union.

Clause 41

LORD BETHELL

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

Clause 41 - *continued*

(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(1A) and (2), 8(1A) and (2) or 12(1A) and (2)(as the case may be)."

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

LORD PATEL
LORD MACKAY OF CLASHFERN

127 Page 24, line 9, after "consult" insert "patients and end users directly affected by the regulations, and any other"

BARONESS THORNTON
LORD HUNT OF KINGS HEATH

128 Page 24, line 9, leave out from "consult" to end and insert "—

(a) healthcare organisations;

(b) pharmaceutical organisations;

(c) veterinary organisations;

(d) medical research organisations;

(e) patient representatives' organisations; and

(f) any other such persons the authority considers appropriate."

Member's explanatory statement
This amendment strengthens the consultation provisions.

LORD SHARKEY
BARONESS JOLLY

129 Page 24, line 9, at end insert "which must include—

(i) representatives of the relevant patient groups,

(ii) medical research charities,

(iii) the pharmaceutical industry,

(iv) academic researchers;

(b) publish on its website in advance of each consultation the—

(i) terms, start date and length of that consultation,

(ii) proposed consultees, and

(iii) proposed date and method of the publication of its results."

Clause 41 - *continued*

BARONESS THORNTON
LORD HUNT OF KINGS HEATH

130 Page 24, line 19, leave out subsection (3)

Member's explanatory statement
This probing amendment removes the provision which enables the consultation requirements to have been satisfied by consultations that took place prior to the passing of this Act.

After Clause 41

LORD BETHELL

131 Insert the following new Clause—

"Reporting requirements

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

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

(3) A report must include a summary of—

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

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

(4) The reporting periods are—

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

(b) each successive period of 24 months."

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

BARONESS THORNTON
BARONESS BENNETT OF MANOR CASTLE

132 Insert the following new Clause—

"Duty to consult devolved administrations

(1) Before making any regulations under this Act that contain provisions which are within the legislative competence of a devolved legislature, the Secretary of State must consult the Scottish Government, the Welsh Government and the Northern Ireland Executive as relevant, and have regard to their views.

(2) In this section "devolved legislature" means the Scottish Parliament, Senedd Cymru or the Northern Ireland Assembly.

After Clause 41 - *continued*

(3) A provision is within the legislative competence of a devolved legislature if—

(a) it would be within the legislative competence of the Scottish Parliament if it were contained in an Act of the Scottish Parliament;

(b) it would be within the legislative competence of Senedd Cymru if it were contained in an Act of Senedd Cymru (including any provision that could only be made with the consent of a Minister of the Crown); or

(c) the provision, if it were contained in an Act of the Northern Ireland Assembly—

(i) would be within the legislative competence of the Assembly, and

(ii) would not require the consent of the Secretary of State."

Member's explanatory statement
This new Clause requires the Government to consult the devolved administrations and have regard to their views before making regulations.

Clause 42

LORD BETHELL

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

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

Clause 42 - *continued*

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

section 15	(a) the made affirmative procedure, where the regulations contain a declaration that the Secretary of State considers that they need to be made urgently to protect the public from an imminent risk of serious harm to health
	(b) the draft affirmative procedure in any other case
any other provision in Part 1, 2 or 3	the draft affirmative procedure

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

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

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

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

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

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

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

(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

Clause 42 - *continued*

(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."

Member's explanatory statement

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

BARONESS THORNTON
LORD HUNT OF KINGS HEATH

134 Page 24, line 40, leave out subsections (4) to (9) and insert—

"(4) Subject to subsection (11), regulations of a Northern Ireland department acting alone under section 1(1) or 8(1) may not be made unless a draft of the regulations has been laid before and approved by a resolution of the Northern Ireland Assembly.

(5) Subject to subsection (15), a statutory instrument containing regulations of the Secretary of State and a Northern Ireland department acting jointly under section 1(1) or 8(1) may not be made unless a draft of the instrument has been laid before and approved by a resolution of—

(a) each House of Parliament, and

(b) the Northern Ireland Assembly.

(6) A statutory instrument containing regulations of the Secretary of State acting alone to which subsection (16) applies may be made without a draft of the instrument being laid before, and approved by a resolution of, each House of Parliament.

(7) A statutory instrument containing regulations made under subsection (6) must be laid before Parliament after being made.

(8) Regulations contained in an instrument made in accordance with subsection (6) cease to have effect at the end of the period of 28 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.

(9) In calculating the period of 28 days for the purpose of subsection (8), 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 four days.

(10) Where regulations cease to have effect as a result of subsection (8), that does not—

(a) affect the validity of anything previously done under the regulations, or

(b) prevent the making of new regulations.

(11) Regulations of a Northern Ireland department acting alone to which subsection (16) applies are subject to the made affirmative procedure.

(12) For the purposes of subsection (11), "subject to the made affirmative procedure" means that the regulations—

(a) must be laid before the Northern Ireland Assembly as soon as reasonably practicable after being made, and

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

(13) In calculating the period of 40 days mentioned in subsection (12)(b), no account is to be taken of any time during which the Northern Ireland Assembly is—

(a) dissolved,

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

Clause 42 - *continued*

(c) adjourned for more than six days.

(14) Where by virtue of this section a Northern Ireland department makes regulations that are subject to the made affirmative procedure and the regulations cease to have effect because they are not approved within the period mentioned in subsection (12)(b), the fact that the regulations cease to have effect does not—

(a) affect anything previously done under or by virtue of the regulations, or

(b) prevent the making of new regulations.

(15) A statutory instrument containing regulations of the Secretary of State and a Northern Ireland department acting jointly to which subsection (16) applies is subject to—

(a) the made affirmative procedure in Parliament (as described in subsections (6) to (10)), and

(b) the made affirmative procedure in the Northern Ireland Assembly (as described in subsections (12) to (14)).

(16) This subsection applies to regulations that contain only provision made in reliance on—

(a) section 6, 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; or

(b) section 15, 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."

Member's explanatory statement

This amendment removes provision for certain regulations to be subject to the negative procedure and would thus require all regulations to be subject to the affirmative procedure. In declared urgent cases, regulations would be subject to the made affirmative procedure, rather than the negative procedure as the Bill currently allows for.

LORD SHARKEY
LORD FORSYTH OF DRUMLEAN
BARONESS ANDREWS

135 Page 25, line 8, leave out from "to" to "if" in line 9 and insert "the made affirmative procedure"

LORD SHARKEY

136 Page 25, line 12, leave out from beginning to "if" in line 13 and insert "the confirmatory procedure under the Statutory Rules (Northern Ireland) Order 1979"

LORD PATEL
LORD PANNICK
LORD MACKAY OF CLASHFERN

137 Page 25, line 27, leave out sub-paragraph (iii)

Member's explanatory statement
This amendment will require that regulations under Clause 6 are subject to the affirmative resolution procedure.

138 Page 25, line 34, leave out sub-paragraph (vii)

Member's explanatory statement
This amendment will require that regulations under Clause 15 are subject to the affirmative resolution procedure.

After Clause 42

LORD SHARKEY
BARONESS JOLLY

139 Insert the following new Clause—

"Expiry of powers

All the powers to make regulations contained in this Act expire at the end of the period of three years beginning with the day on which this Act is passed."

BARONESS THORNTON
LORD HUNT OF KINGS HEATH

140 Insert the following new Clause—

"Time limits on delegated powers

Sections 1, 8, 12 and 16 of this Act, and the powers they confer, expire at the end of the period of two years beginning with the day on which they come into force."

Member's explanatory statement
This new Clause would ensure that the delegated powers are time limited to 2 years.

LORD PATEL
LORD PANNICK
LORD MACKAY OF CLASHFERN

141 Insert the following new Clause—

"Expiry of powers

Sections 1, 8, and 12 and the powers conferred under those sections expire at the end of the period of three years beginning with the day on which this Act is passed."

Member's explanatory statement
This amendment is a sunset Clause on sections 1, 8 and 12 of the Bill.

LORD SHARKEY
LORD FORSYTH OF DRUMLEAN
BARONESS ANDREWS
BARONESS JOLLY

142 Insert the following new Clause—

"Made affirmative procedure

A statutory instrument containing regulations subject to the made affirmative procedure must be laid before Parliament as soon as reasonably practicable after being made and 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."

LORD SHARKEY
LORD FORSYTH OF DRUMLEAN
BARONESS ANDREWS

143 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.

After Clause 42 - *continued*

(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."

144 Insert the following new Clause—

"Super-affirmative procedure: Northern Ireland

(1) For the purposes of section 1(1), section 8(1), section 12(1) and section 16(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 (2)(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 44

LORD SHARKEY
BARONESS JOLLY

145 Leave out Clause 44 and insert the following new Clause—

"**Commencement**

This Act comes into force on the day on which it is passed."

Schedule 1

BARONESS THORNTON
LORD HUNT OF KINGS HEATH

146 Page 34, line 10, leave out "have regard to" and insert "act in accordance with"

Member's explanatory statement
This amendment places a duty on the Secretary of State to follow, rather than have regard to, guidance.

Medicines and Medical Devices Bill

SIXTH

MARSHALLED

LIST OF AMENDMENTS

TO BE MOVED

IN GRAND COMMITTEE

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12 November 2020
