Medicines and Medical Devices Bill

AMENDMENTS

TO BE MOVED

ON REPORT

Clause 1

BARONESS THORNTON

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.

As an amendment to the Amendment to Clause 1, page 1, line 9 in the name of Lord Bethell

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.

BARONESS BENNETT OF MANOR CASTLE

Page 1, line 14, at end insert—

"(ba) the protection of the environment;"

BARONESS THORNTON

As an amendment to the Amendment to Clause 1, page 1, line 17 in the name of Lord Bethell

at end insert—

"( ) 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.

( ) 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 7

BARONESS THORNTON

As an amendment to the Amendment to Clause 7, page 5, line 8 in the name of Lord Bethell

at end insert—

"( ) 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.

As an amendment to the Amendment to Clause 7, page 5, line 21 in the name of Lord Bethell

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.

After Clause 7

LORD PATEL
BARONESS THORNTON
LORD KAKKAR
LORD MACKAY OF CLASHFERN

This amendment replaces an amendment tabled in the name of Lord Patel, published on daily sheet 154(d)

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

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.

As an amendment to the Amendment to Clause 9, page 6, line 33 in the name of Lord Bethell

at end insert—

"( ) 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.

( ) 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.

After Clause 12

LORD PATEL
BARONESS THORNTON
LORD KAKKAR

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

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.

As an amendment to the Amendment to Clause 14, page 9, line 40 in the name of Lord Bethell

at end insert—

"( ) 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.

( ) 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 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.

After Clause 18

BARONESS THORNTON

As an amendment to the new Clause after Clause 18 in the name of Lord Bethell

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 the new Clause after Clause 18 in the name of Lord Bethell

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 the new Clause after Clause 18 in the name of Lord Bethell

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.

After Clause 39

LORD PATEL
BARONESS THORNTON
LORD KAKKAR

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.

After Clause 40

BARONESS THORNTON

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 44

BARONESS THORNTON

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.

Medicines and Medical Devices Bill

AMENDMENTS

TO BE MOVED

ON REPORT

---

6 January 2021
