

# Medicines and Medical Devices Bill

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AMENDMENTS  
TO BE MOVED  
IN GRAND COMMITTEE

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**After Clause 37**

BARONESS THORNTON

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.*

**Clause 42**

BARONESS THORNTON  
LORD HUNT OF KINGS HEATH

*Re-tabled version of the amendment printed on HL Bill 116(a)*

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.

**Clause 42 - continued**

- (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
  - (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)).

**Clause 42 - continued**

- (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.*

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*22 September 2020*

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