Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 5

REGULATIONS UNDER PARTS 1, 2, 3 AND 4

47 Procedure

(1) Any power to make regulations under a provision of Part 1, 2, 3 or 4 so far as exercisable by the Secretary of State, or by the Secretary of State acting jointly with a Northern Ireland department, is exercisable by statutory instrument.

(2) Any power to make regulations under section 2(1) **[**[F1], 7A(1)**]** or 10(1) so far as exercisable by a Northern Ireland department (other than when acting jointly with the Secretary of State) is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979 (S.I. 1979/1573 (N.I. 12)) (and not by statutory instrument).

(3) The procedure for making regulations under Part 1, 2, 3 or 4 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 6(1)(a)	the negative procedure
section 12(1)(a)	the negative procedure
section 17(1)(a)	the negative procedure
paragraph 9 of Schedule 2	the negative procedure
section 7	(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 18	(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
any other provision of Part 1, 2, 3 or 4	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

(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 a Northern Ireland department 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 a Northern Ireland department 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.

Textual Amendments

F1 Word in s. 47(2) inserted (1.7.2022) by Health and Care Act 2022 (c. 31), **ss. 101(9)**, 186(6); S.I. 2022/734, reg. 2(a), **Sch.** (with regs. 13, 29, 30)

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Section 47.