Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 5

REGULATIONS UNDER PARTS 1, 2, 3 AND 4

43 Power to make consequential etc provision

(1) This section applies to regulations under a power in Part 1, 2, 3 or 4, apart from regulations under paragraph 9 of Schedule 2.

(2) The regulations may—

(a) make consequential, supplementary, incidental, transitional, transitory or saving provision;

(b) make different provision for different purposes;

(c) make different provision for different areas;

(d) make provision for all cases to which the power applies or for those cases subject to specified exceptions or for any specified cases or descriptions of case.

44 Scope of powers of Northern Ireland departments

No provision may be made by a Northern Ireland department acting alone in regulations under section 2(1) or 10(1) unless the provision, if it were contained in an Act of the Northern Ireland Assembly—

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

(b) would not require the consent of the Secretary of State.

45 Consultation

(1) Before making regulations under a provision of Part 1, 2, 3 or 4, the relevant authority must carry out a public consultation.

(2) In relation to proposed regulations under section 19(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.

(3) In relation to proposed regulations under section 2(1), 10(1) or 15(1), the consultation document must include a summary of the relevant authority's assessment of the matters mentioned in section 2, 10 or 15 (as the case may be).

(4) The duty to consult imposed by subsection (1) does not apply in relation to regulations that contain only provision made in reliance on—

(a) section 7 (disapplication of provisions relating to human medicines where there is a risk of serious harm to health), or

(b) section 18 (disapplication of provisions relating to medical devices where there is a risk of serious harm to health),

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.

(5) The duty to consult imposed by subsection (1) may be satisfied by consultation carried out before this Act was passed.

(6) In this section, "the relevant authority" means—

(a) in relation to regulations made under section 2(1) or 10(1), the appropriate authority within the meaning given by section 2(6) or 10(6) as the case may be, and

(b) in relation to any other regulations, the Secretary of State.

46 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 2(1), 10(1), 15(1) and 19(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 2(1), 10(1), 15(1) or 19(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 2(1), 10(1), 15(1) or 19(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 2(1) or 10(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 2(1) or 10(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 15(1) or 19(1), the Secretary of State.

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) 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

If the regulations contain provision made in reliance on	*the regulations are subject to*
	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.