

Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 5

REGULATIONS UNDER PARTS 1, 2, 3 AND 4

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), [^{F1}7A(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), [^{F2}7A(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), $[^{F3}7A(1),]$ 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-

Changes to legislation: There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Section 46. (See end of Document for details)

- (a) in relation to regulations made under section 2(1) [^{F4}, 7A(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) [^{F4}, 7A(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.

Textual Amendments

- **F1** Word in s. 46(1) inserted (1.7.2022) by Health and Care Act 2022 (c. 31), ss. 101(8)(a), 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)
- F2 Word in s. 46(3)(b) inserted (1.7.2022) by Health and Care Act 2022 (c. 31), ss. 101(8)(a), 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)
- **F3** Word in s. 46(4)(a) inserted (1.7.2022) by Health and Care Act 2022 (c. 31), ss. 101(8)(a), 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)
- **F4** Word in s. 46(5) inserted (1.7.2022) by Health and Care Act 2022 (c. 31), **ss. 101(8)(b)**, 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 46.