Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 5

REGULATIONS UNDER PARTS 1, 2, 3 AND 4

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.

[[F1](1A) In relation to proposed regulations under section 7A(1), the Secretary of State must—

(a) where the regulations relate to Wales, specifically consult the Welsh Ministers, and

(b) where the regulations relate to Scotland, specifically consult the Scottish Ministers.**]**

(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—

[F2(a) in relation to regulations made under section 2(1) or 7A(1), the appropriate authority within the meaning given by section 2(6),

(aa) in relation to regulations made under section 10(1), the appropriate authority within the meaning given by section 10(6),**]** and

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

Textual Amendments

F1 S. 45(1A) inserted (1.7.2022) by Health and Care Act 2022 (c. 31), **ss. 101(7)(a)**, 186(6); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)

F2 S. 45(6)(a)(aa) substituted for s. 45(6)(a) (1.7.2022) by Health and Care Act 2022 (c. 31), **ss. 101(7)(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 45.