Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 4

MEDICAL DEVICES

CHAPTER 1

REGULATIONS: GENERAL

15 Power to make regulations about medical devices

(1) The Secretary of State may by regulations make provision specified in sections 16 to 18 amending or supplementing the Medical Devices Regulations 2002 (S.I. 2002/618).

(2) In making regulations under subsection (1), the Secretary of State's overarching objective must be safeguarding public health.

(3) In considering whether regulations under subsection (1) would contribute to this objective, the Secretary of State must have regard to—

(a) the safety of medical devices;

(b) the availability of medical devices;

(c) the likelihood of the United Kingdom being seen as a favourable place in which to—

(i) carry out research relating to medical devices,

(ii) develop medical devices, or

(iii) manufacture or supply medical devices.

(4) Where regulations under subsection (1) may have an impact on the safety of medical devices, the Secretary of State may make the regulations only if the Secretary of State considers that the benefits of doing so outweigh the risks.

16 Manufacture, marketing and supply

(1) Regulations under section 15(1) may make provision about—

(a) requirements that must be met in relation to medical devices in order for them to be marketed, put into service or otherwise supplied ("relevant requirements"), including—

(i) requirements in terms of design, manufacture, composition or other characteristics of the devices, or

(ii) requirements imposed on persons involved in marketing or supplying the devices,

(b) assessments of whether relevant requirements are met in relation to medical devices,

(c) who may carry out such assessments, including provision about the appointment of one or more persons (whether or not established in the United Kingdom) who meet criteria set out in the regulations—

(i) to assess whether relevant requirements are met, and

(ii) if appropriate, to confirm that they are,

(d) treating confirmation that relevant requirements are met given by one or more persons who are not appointed under provision made in reliance on paragraph (c) in the same way as confirmation given by a person who is so appointed,

(e) the making of declarations confirming that relevant requirements are met,

(f) requirements that medical devices carry evidence that relevant requirements are met, including evidence that confirmation has been given as mentioned in paragraph (c) or (d),

(g) the packaging of medical devices, and information, labelling or instructions to be supplied on, with or in relation to them,

(h) one or more registers of medical devices, their manufacturers or their suppliers, including provision—

(i) conferring functions relating to establishing and maintaining a register,

(ii) requiring information in relation to a medical device to be entered in a register, and

(iii) permitting or requiring some or all of the information entered in a register to be made publicly available,

(i) investigations into or evaluations of the safety or performance, including the clinical effectiveness, of medical devices, or

(j) surveillance of the market in medical devices.

(2) Provision made in reliance on subsection (1)(a) may (among other things) identify relevant requirements by reference to international agreements or standards relating to the marketing or supply of medical devices, including agreements or standards as they have effect from time to time.

17 Fees, information, offences

(1) Regulations under section 15(1) may make provision—

(a) about the charging of fees in connection with the exercise of a function conferred by a medical devices provision, including the charging of fees by a person appointed under provision made in reliance on section 16(1)(c),

(b) about the recording of information regarding the safety and performance, including the clinical effectiveness, of medical devices, including the extent to which relevant requirements that apply in relation to the devices are met,

(c) permitting or requiring such information to be disclosed to the Secretary of State or to a person appointed under provision made in reliance on section 16(1)(c), or

(d) amending the Schedule to the Medical Devices Regulations 2002 (S.I. 2002/618) inserted by Schedule 3 to this Act (list of regulations breach of which is an offence under regulation 60A).

(2) In **[**F1this Chapter**]**, "medical devices provision" means a provision in—

(a) regulations under section 15(1), or

(b) the Medical Devices Regulations 2002.

Textual Amendments

F1 Words in s. 17(2) substituted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **28(2)**

Commencement Information

I1 S. 17(2) in force at 11.2.2021 see s. 50(1)(g)

18 Emergencies

(1) Regulations under section 15(1) may make provision about the disapplication of a medical devices provision in circumstances which give rise to a need to protect the public from a risk of serious harm to health.

(2) Regulations made in reliance on subsection (1) may provide for the disapplication to be subject to—

(a) conditions set out in the regulations;

(b) conditions set out in a protocol published by the Secretary of State.

(3) Where regulations made in reliance on subsection (1) provide that the Secretary of State may publish a protocol setting out conditions, the regulations must provide—

(a) that the Secretary of State may withdraw or amend the protocol, and

(b) that the protocol is to have effect only for a period of time specified in the protocol.

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, CHAPTER 1.