Medicines and Medical Devices Act 2021

2021 CHAPTER 3

PART 4

MEDICAL DEVICES

CHAPTER 1

REGULATIONS: GENERAL

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,

***Changes to legislation:** There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Section 16. (See end of Document for details)*

(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.

Changes to legislation:
There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, Section 16.