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**Changes to legislation:** There are currently no known outstanding effects for the Medicines and Medical Devices Act 2021, SCHEDULE 1. (See end of Document for details)

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## SCHEDULES

### SCHEDULE 1

Section 1

#### FURTHER PROVISION ABOUT THE COMMISSIONER FOR PATIENT SAFETY

##### *Principles relating to core duties*

- 1 (1) The Commissioner must prepare and publish a set of principles to govern the way in which the Commissioner will carry out the Commissioner's core duties.
- (2) The Commissioner—
  - (a) may revise the principles, and
  - (b) must publish any revised version.
- (3) The Commissioner must carry out a public consultation in preparing or revising the principles.

##### *Involvement of patients*

- 2 (1) The Commissioner must take reasonable steps to involve patients in the discharge of the Commissioner's core duties.
- (2) The Commissioner must in particular take reasonable steps to—
  - (a) ensure that patients are aware of the Commissioner's core duties and of how they may communicate with the Commissioner, and
  - (b) consult patients, or persons who appear to the Commissioner to represent the interests of patients, on matters which the Commissioner proposes to consider in the discharge of the core duties.

##### *Supplementary functions and information*

- 3 (1) For the purposes of carrying out the core duties, the Commissioner may—
  - (a) make a report or recommendation to a relevant person;
  - (b) consult or receive information from patients or any other person the Commissioner thinks appropriate;
  - (c) request information from a relevant person;
  - (d) share information with a relevant person.
- (2) A relevant person to whom a report or recommendation is made under subparagraph (1)(a) must provide a response to that report or recommendation within such period as the Commissioner may reasonably require.
- (3) A relevant person must, so far as reasonably practicable, comply with a request by the Commissioner to provide information within such period as the Commissioner may reasonably require.

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- (4) Nothing in this Schedule authorises a disclosure of information which contravenes the data protection legislation (but in determining whether a disclosure would do so, take into account the powers conferred by this Schedule).
- (5) In this paragraph—
- “data protection legislation” has the meaning given by section 3(9) of the Data Protection Act 2018;
- “health care” means all forms of health care provided for individuals, whether relating to physical or mental health, and including ancillary care;
- “relevant person” means—
- (a) a person who exercises functions of a public nature, relating to medicines or medical devices, so far as those functions are exercisable in relation to England;
  - (b) any other person who, in the course of providing health care, provides services relating to medicines or medical devices in relation to England.

*Individual cases*

- 4 (1) The Commissioner may not exercise functions in relation to an individual case.
- (2) But sub-paragraph (1) does not prevent the Commissioner considering individual cases and drawing conclusions about them for the purpose of, or in the context of, considering a general issue.

*Amendments to primary legislation*

- 5 (1) In Part 1 of the Table at the end of paragraph 3 of Schedule 1 to the Public Records Act 1958 (definition of public records), at the appropriate place insert— “ Commissioner for Patient Safety. ”
- (2) In Part 3 of Schedule 1 to the House of Commons Disqualification Act 1975 (offices disqualifying for membership), at the appropriate place insert— “ Commissioner for Patient Safety. ”
- (3) In Part 6 of Schedule 1 to the Freedom of Information Act 2000 (other public bodies and offices: general), at the appropriate place insert— “ The Commissioner for Patient Safety. ”
- (4) In section 71 of the National Health Service Act 2006 (schemes for meeting losses and liabilities etc of certain health service bodies), in subsection (2), before paragraph (h) insert—
- “(ga) the Commissioner for Patient Safety,”.
- (5) In Part 1 of Schedule 19 to the Equality Act 2010 (authorities subject to the public sector equality duty), in the group of entries under the heading “Health, social care and social security”, at the appropriate place insert— “ The Commissioner for Patient Safety. ”

*Regulations about appointment and operation*

- 6 (1) The Secretary of State may by regulations make such provision as the Secretary of State considers appropriate with regard to the appointment and operation of the Commissioner.

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- (2) Regulations under sub-paragraph (1) may (among other things) contain provision for and about—
- (a) the Commissioner's terms of office;
  - (b) remuneration or other benefits;
  - (c) the provision of financial or other assistance, including staff, accommodation, equipment or other facilities, for the Commissioner;
  - (d) requirements to prepare business plans;
  - (e) requirements to prepare reports;
  - (f) requirements to lay documents before Parliament;
  - (g) requirements to provide documents to the Secretary of State or other persons specified in the regulations;
  - (h) the conferring of functions on other persons in relation to the Commissioner;
  - (i) the appointment of a board to provide advice to the Commissioner.

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