
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision about the appointment and operation of the Commissioner for Patient Safety (the “Commissioner”) established under the Medicines and Medical Devices Act 2021 (c. 3).

Regulation 2 defines financial year, initially, by reference to the date the first Commissioner starts in the role, with subsequent financial years being for a period of 12 months, ending with 31st March each year.

Regulation 3 provides that the Commissioner will serve for a term of three years and that a Commissioner will be eligible for one further term only. It also provides for the resignation of a Commissioner, or removal by the Secretary of State of the Commissioner if that person has become unfit or unable to properly discharge their functions, or if they have behaved in a way that is not compatible with them continuing in office.

Regulations 4 to 6 provide for the Commissioner to receive remuneration, the funding of the role and for the provision of staff and facilities.

Regulation 7 provides for the preparation of a business plan setting out, in relation to the discharge of the Commissioner’s functions, what the Commissioner’s proposed main activities for the period covered by the plan will be, including any areas or matters the Commissioner intends to consider, and what the Commissioner’s proposed strategic priorities for that period will be.

Regulation 8 requires the Commissioner to keep accounting records and prepare a statement of accounts for each financial year.

Regulation 9 requires the Commissioner to publish an annual report detailing the way in which the Commissioner has discharged their functions and what they have found in the course of exercising these functions during the year.

Regulation 10 requires the Commissioner to appoint an advisory panel to provide advice and assistance relating to the discharge of the Commissioner’s functions and encourage good practice in involvement with patients.

Regulation 11 enables the Commissioner to authorise members of staff to carry out any of the Commissioner’s functions.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen.