EXPLANATORY MEMORANDUM TO

THE COMMISSIONER FOR PATIENT SAFETY (APPOINTMENT AND OPERATION) (ENGLAND) REGULATIONS 2022

2022 No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care ("DHSC") and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The Commissioner for Patient Safety was a newly established position within the Medicines and Medical Devices Act 2021. The Commissioner's core duties are to promote: the safety of patients with regard to the use of medicines and medical devices; and the importance of the views of patients and other members of the public, in relation to the safety of medicines and medical devices. This instrument sets out provisions regarding the terms of appointment and operation of the Commissioner for Patient Safety.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England.

5. European Convention on Human Rights

5.1 Maria Caulfield MP, Parliamentary Under Secretary of State for Patient Safety and Primary Care at the Department of Health and Social Care has made the following statement regarding Human Rights:

"In my view the provisions of The Commissioner for Patient Safety (Appointment and Operation) (England) Regulations 2022 are compatible with the Convention rights."

6. Legislative Context

6.1 The Medicines and Medical Devices Act 2021 received Royal Assent on 11 February 2021 and Part 1 came into force on 11 April 2021. Part 1 is about the Commissioner for Patient Safety, and section 1 establishes the Commissioner position and sets out its "core duties".

6.2 Under the Medicines and Medical Devices Act 2021 (paragraph 6 of Schedule 1) the Secretary of State is able to make legislative provisions about the appointment and operation of the Commissioner for Patient Safety. This instrument is the first use of this ability.

7. Policy background

What is being done and why?

7.1 This instrument puts provisions in place about the appointment and operation of the Commissioner for Patient Safety. This legislative detail is needed to facilitate that the Commissioner role is operational and functional.

Explanations

What did any law do before the changes to be made by this instrument?

7.2 Part 1 of the Medicines and Medical Devices Act 2021 is about the Commissioner for Patient Safety, and section 1 establishes the Commissioner position and sets out its "core duties".

7.3 Schedule 1 of the Medicines and Medical Devices Act 2021 sets out further provision about the Commissioner.

Why is it being changed?

7.4 Secondary legislation is needed to add further provisions regarding the appointment and operation of the Commissioner for Patient Safety to ensure that the Commissioner role is operational.

What will it now do?

7.5 This instrument will set out further provisions regarding the appointment and operation of the Commissioner for Patient Safety. Specifically, this will provide a legislative framework for details on the Commissioner's:

- Term of office- The Commissioner for Patient Safety will serve for an initial term of 3 years.
- Reappointment- The Commissioner for Patient Safety will be eligible for reappointment after having held office and that they may resign or be removed by the Secretary of State, if appropriate.
- Remuneration- The Commissioner for Patient Safety shall receive remuneration.
- Funding- The Secretary of State will fund the operation of the Commissioner for Patient Safety.
- Business plan- The Commissioner for Patient Safety will produce a business plan covering a period of at least 12 months.
- Accounting- The Commissioner for Patient Safety is to keep proper accounts each financial year and provide a copy to the Secretary of State.
- Annual report- The Commissioner for Patient Safety shall publish an annual report to explain the activities they have undertaken during the year in relation to their core duties, a copy of which is to be sent to the Secretary of State and laid before each House of Parliament.
- Advisory panel- The Commissioner for Patient Safety must appoint an advisory panel, whose members will have a broad range of relevant interests which are relevant to the Commissioner's functions.
- Powers to confer functions on others- The Commissioner for Patient Safety's staff, so far as authorised by the Commissioner, may exercise any of the Commissioner's functions.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 This instrument does not consolidate any legislation.

10. Consultation outcome

10.1 As required by the Medicines and Medical Devices Act 2021, a public consultation was completed for a period of eight weeks running from 10 June 2021 to 5 August 2021. The consultation sought feedback from those who may be affected by, or have a particular interest in, the set up and functions of the new Commissioner for Patient Safety for England. The consultation specifically sought views on the detail on the appointment and operation of the Commissioner, such as their terms of office, funding, and reporting.

10.2 61 respondents, comprised of 34 organisations and 27 individuals, responded to this consultation. Each of the nine proposals consulted on were supported by more than half of respondents, ranging from 59% to 91% in agreement. The government has now published its response to the consultation and this is available at https://www.gov.uk/government/consultations/the-appointment-and-operation-of-the-patient-safety-commissioner.

11. Guidance

11.1 DHSC does not intend to provide further guidance on the instrument.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 A full Impact Assessment has not been prepared for this instrument because it has been assessed to have a low level of impact on businesses.

13. Regulating small business

13.1 This instrument does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this instrument is for DHSC to periodically review the instrument, as necessary, to ensure that it is still appropriate and effective.

14.2 This instrument does not include a statutory review clause.

15. Contact

15.1 Janet Smith at the Department of Health and Social Care, Telephone: 0113 254 6898 or email: Janet.smith@dhsc.gov.uk , can be contacted with any queries regarding this instrument.

15.2 Ayodamola Abiola at the Department of Health and Social Care, Telephone: 07944251858 or email: Ayodamola.abiola@dhsc.gov.uk, can be contacted with any queries regarding this instrument.

15.3 Laura Lucking and Verity Prime, Deputy Directors for Quality, Patient Safety and Maternity, at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.

15.4 Maria Caulfield MP, Parliamentary Under Secretary of State for Patient Safety and Primary Care at the Department of Health and Social Care can confirm that this explanatory memorandum meets the required standard.