EXPLANATORY MEMORANDUM TO

THE PHARMACY (RESPONSIBLE PHARMACISTS, SUPERINTENDENT PHARMACISTS ETC.) ORDER 2022

2022 No. [XXXX]

1. Introduction

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

2. Purpose of the instrument

2.1 The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (the "Order") makes changes to the Medicines Act 1968 ("the Act"), the Pharmacy Order 2010, the Pharmacy (Northern Ireland) Order 1976 and the Health Act 2006. The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008, are also revoked but transitionally saved pending the first rules by the General Pharmaceutical Council (GPhC) as regards Great Britain and the first regulations of the council of the Pharmaceutical Society of Northern Ireland (PSNI) as regards Northern Ireland.

2.2 This Order clarifies and strengthens the organisational governance arrangements of registered pharmacies, specifically to define and clarify the core purpose of two distinct roles that registered pharmacists undertake – the Responsible Pharmacist and Superintendent Pharmacist - in primary legislation, with professional regulation defining how that purpose is fulfilled.

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, Wales, Scotland and Northern Ireland, except that where amendments are made to other legislation of more limited extent, those amendments have the same extent as the legislation being amended.

4.2 The territorial application of this instrument is England, Wales, Scotland and Northern Ireland, except that where amendments are made to other legislation or provisions of legislation of more limited application, those amendments have the same application as the legislation being amended.

4.3 Pharmacy regulation is a fully devolved matter as regards to Northern Ireland.

5. European Convention on Human Rights

5.1 The Parliamentary Under-Secretary of State for Primary Care and Patient Safety, Maria Caulfield has made the following statement regarding Human Rights:

"In my view the provisions of The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 are compatible with the Convention rights."

6. Legislative Context

6.1 This Order makes changes to legislation to clarify and strengthen the essential role and responsibilities of the Superintendent Pharmacist (SP) and Responsible Pharmacists (RP) in primary legislation, whilst empowering the professional regulators (The GPhC in respect of Great Britain and PSNI in respect of Northern Ireland) to define those roles and responsibilities.

6.2 Currently, section 71 of the Act requires that a corporate body lawfully conducting a retail pharmacy business must:

- Have an SP who is a pharmacist;
- Organise itself so that the keeping, preparing and dispensing of Prescription Only Medicines (POMs) and Pharmacy (P) medicinal products by that business is under the management of that SP;
- That SP must have produced a statement in writing signed by them and on behalf of the body corporate specifying their name and stating whether or not they are on the board of the body corporate; and
- That SP cannot act in a similar capacity for another body corporate.

6.3 The Act does not provide any further detail about the role of an SP, which has allowed for diverse interpretations of the law. While variation can be helpful, we believe a common framework may provide a more consistent basis for on-going development of the SP role.

6.4 Under the Act, in order for a retail pharmacy business to be considered lawful there must be an RP in charge of that business whose duty it is to secure its safe and effective running so far as concerns the sale and supply of medicinal products.

6.5 The provisions in respect of the RP and associated regulation making powers are contained in Part 4 of the Act, and in particular section 72A. The roles and responsibilities of the RP are outlined in detail in the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008 ("the RP Regulations"). Developments in professional leadership and regulation since the RP Regulations came into force, as well as evolving government policy on better regulation, in the context of the overall aims for the "rebalancing" programme, have encouraged a review and impetus to reduce the level of detail in the Act and in current Ministerial legislation in respect to the RP role.

7. Policy background

What is being done and why?

7.1 The Order seeks to clarify and strengthen the organisational governance arrangements for registered pharmacies, specifically to define and clarify the core purpose of the SP and RP in primary legislation with professional regulation defining how that purpose is fulfilled.

7.2 This Order introduces additional requirements of and creates a statutory general duty for an SP within primary legislation in the Medicines Act 1968. It also clarifies the statutory general duty of the RP within the Medicines Act 1968.

7.3 This Order takes the powers to make provision about the RP's statutory responsibilities from Ministers under section 72A of the Act and gives them to the pharmacy regulators so that they can make rules or regulations in relation to this instead. Under this Order, the RP Regulations are revoked but transitionally saved pending the first rules made by the GPhC as regards RP's in Great Britain and the first regulations of the council of the PSNI as regards RP's in Northern Ireland.

7.4 This Order amends legislation so as to give the pharmacy regulators additional powers within the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976, to include a description of the professional responsibilities of RP's and SP's as part of the standards that they set in relation to conduct and performance.

7.5 The Order will rebalance:

- criminal law and professional regulation, so that matters within the ambit of the pharmacy regulators, the GPhC and the PSNI, are dealt with by them and by registration sanctions, rather than by the criminal courts;
- ministerial powers and the powers of the pharmacy regulators, so that pharmacy practice matters are more appropriately set by pharmacy regulators and less by government Ministers;
- legislation and standards, so that pharmacy practice standards are set and enforced by pharmacy regulators and less by inflexible legislation. Underpinning this is an "outcomes"-based approach: i.e. the safe and effective practice of pharmacy should be the required outcome rather than binding the professions to particular ways of doing things; and
- the relationship between pharmacy owners, RPs and SPs to ensure safe and effective practice of pharmacy in a retail pharmacy context, making clear the accountability of: the RP, who is in charge of a particular pharmacy on a given day; the SP, who is generally responsible for the safe and effective supply of medicinal products across all branches of a retail pharmacy business and who is intended to be the professional lead within a body corporate; and the pharmacy owner.

7.6 In transferring the powers from Ministerial legislation to the Regulators, it is appropriate that certain safeguards are put in place. The relevant pharmacy regulators would need to consult on any such standards. It is proposed that before making rules under section 72A, the GPhC must publish draft rules and invite representations from Ministers and other appropriate persons to consult on those draft rules. In Great Britain, the resultant rules cannot enter into force until approved by the Privy Council and will then be subject to the "negative resolution" procedure in the UK Parliament. Separately, any regulations made under section 72A by the Council of the PSNI would require consultation of appropriate persons and consultation and approval by the Department of Health in Northern Ireland.

7.7 The Order also makes two changes that apply to Northern Ireland only. The Order amends the Pharmacy (Northern Ireland) Order 1976 so that the Department of Health in Northern Ireland may appoint a deputy registrar – the person who holds and maintains the professional registers in relation to pharmacy. The Order also amends the Act so as to require Superintendent Pharmacists in Northern Ireland to notify the

PSNI when they stop being a Superintendent Pharmacist. This aims to align the law in Northern Ireland with that of Great Britain.

8. European Union Withdrawal and Future Relationship

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

9. Consolidation

9.1 There are no plans to consolidate the legislation.

10. Consultation outcome

10.1 A UK-wide public consultation ran from 19 June 2018 until 11 September 2018. The consultation was separated into two parts: Part 1 being in respect of the draft Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order, and Part 2 being in respect of the draft Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order.

10.2 To encourage responses to the consultation, officials from the Department of Health and Social Care and the Devolved Administrations supported a number of engagement events across the United Kingdom during the consultation period. The aim was to ensure that stakeholders understood the proposals fully and had an opportunity to raise their comments and concerns for clarification.

10.3 In total, 632 responses were received to the consultation. Responses were received from a mix of pharmacy professionals, representative groups, organisations and public-sector bodies. Of the total respondents, 558 answered questions on Part 2.

10.4 Responses to Part 2 of the consultation indicated high levels of support for most of the proposals. However, several proposals had a lower level of support indicated by respondents. Where this was the case, this was determined to be as a result of dissatisfaction with matters not subject to the consultation and action has been agreed by the Rebalancing Programme Board to address relevant concerns, where deemed appropriate.

10.5 The changes will apply to Great Britain and Northern Ireland. Officials from the Department of Health and Social Care have engaged with officials in the Devolved Administrations to develop the policy and agreed that the consultation should be taken forward on a UK-wide basis.

10.6 Full details of the consultation and the Government's response can be found at: Pharmacy legislation on dispensing errors and organisational governance - GOV.UK (www.gov.uk).

11. Guidance

11.1 The Department of Health and Social Care does not propose to issue any guidance in relation to this Order. Standards for registered pharmacy professionals are a matter for consideration by the General Pharmaceutical Council and the Pharmaceutical Society of Northern Ireland. The pharmacy regulators must consult on any proposed rules or regulations, including proposed statutory responsibilities for RPs, offering the opportunity for scrutiny and comment. The current Ministerial regulations will be transitionally saved until the two pharmacy regulators have published their first rules/regulations on the matter.

12. Impact

12.1 The impact on business, charities or voluntary bodies is positive. This analysis finds that the benefits of the policy, conservatively estimated at £516,000 over the next ten years, are likely to outweigh any costs, which we believe to be limited to a one-off cost of £379,000 (as pharmacy staff take time to familiarise themselves with the changes). This gives an estimated Net Present Value (for business) of £137,000 over ten years. Put another way, benefits are likely to be around £3.63 per pharmacy, per year; costs are likely equivalent to £2.67 per pharmacy per year over the ten year timeframe.

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

12.3 An Impact Assessment has not been prepared for this instrument because government rules dictate that an Impact Assessment does not need to be produced if the equivalent Annual Net Direct Cost to Business is less than +/- £5m. It is estimated that the proposed Order will fall below this threshold. Instead, a summary cost-benefit analysis has been undertaken and is summarised in 12.1.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is that the Department of Health and Social Care has committed itself to undertaking a review of the measures introduced by this Order within five years of it being made and a report of the review will be published.

14.2 The Order does not include a statutory review provision and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015 the Parliamentary Under-Secretary of State for Primary Care and Patient Safety, Maria Caulfield, has made the following statement:

"In my view it is not appropriate to include a statutory review provision in the Order because there is no significant annualised net impact on business expected".

15. Contact

15.1 Stephen Knight at the Department of Health and Social Care (telephone: 020 7972 4155 or email: Stephen.Knight@dhsc.gov.uk) can be contacted with any queries regarding the instrument.

15.2 Alette Addison, Deputy Director for Pharmacy, Dentistry and Eyecare, at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Maria Caulfield, Parliamentary Under-Secretary of State for Primary Care and Patient Safety at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.