EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AUTHORISATION BY PHARMACISTS AND SUPERVISION BY PHARMACY TECHNICIANS) ORDER 2025

2025 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 His Majesty.

2. Declaration

2.1 Stephen Kinnock MP, Minister of State for Care, at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.

2.2 Alette Addison Deputy Director of Pharmacy, Eye Care and Controlled Drugs, at the Department of Health and Social care confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Stephen Knight at the Department of Health and Social care, email: communitypharmacyteam@dhsc.gov.uk can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This instrument introduces flexibilities concerning how medicines are prepared, assembled, dispensed, sold and supplied within pharmacy services, and more specifically who oversees and is professionally accountable for these processes.

4.2 This instrument amends the Medicines Act 1968 and The Human Medicines Regulations 2012 to enable pharmacists to authorise pharmacy technicians to carry out, or supervise others to carry out, the preparation, assembly, dispensing, sale, and supply of medicines. It will enable pharmacists to authorise any member of the pharmacy team to hand out prescriptions in their absence that they have checked and are ready to go to the patient without any further intervention from the pharmacist – so called 'checked and bagged prescriptions'. The amendments will also allow pharmacy technicians to take primary responsibility for the preparation, assembly and dispensing of medicinal products in hospital aseptic facilities, for example intravenous chemotherapy drugs, parenteral nutrition and antibiotics in ready-to-administer form.

Where does the legislation extend to, and apply?

4.3 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is the United Kingdom.

4.4 The territorial application of this instrument is England, Scotland and Wales. Only the measure relating to checked and bagged prescriptions will have practical effect in Northern Ireland. The other measures will not apply in Northern Ireland until such

time as pharmacy technicians become a registered profession in Northern Ireland and further legislation is made to bring these measures into effect.

5. Policy Context

What is being done and why?

5.1 This change will enable pharmacists to authorise (without directly supervising) registered pharmacy technicians to perform tasks that would otherwise need to be performed by or under the supervision of pharmacists – and for registered pharmacy technicians to take primary responsibility for the preparation and assembly of medicinal products in hospital aseptic facilities, and in doing so, supervise non-registered members of staff. These proposals are designed to allow pharmacists to spend less time on tasks that can be safely delegated to pharmacy technicians, who are registered and regulated health professionals in Great Britain – capable of working more autonomously, referring to a pharmacist only where necessary.

5.2 This change is designed to enable a broader range of pharmaceutical services to continue safely while pharmacists are engaged delivering clinical services or temporarily absent from the premises. This will make full use of registered pharmacy technicians' knowledge and skills and free-up pharmacist time to deliver more clinical and patient-facing services, and improve patient experience.

What was the previous policy, how is this different?

5.3 Previously the preparation, assembly, dispensing, sale and supply of medicines ordinarily had to be undertaken by, or under the supervision of a pharmacist. These proposals will give pharmacists the option to either supervise these activities as they do now, or authorise these activities to be done by, or under the supervision of, a pharmacy technician.

5.4 Previously, medicines that are ready for collection by a patient or their representative from a bricks and mortar community pharmacy could only be handed out in the presence of a pharmacist. This could result in patient inconvenience and repeat visits to collect the medicines. The changes remove barriers to patients receiving their 'checked and bagged' prescriptions, that is medicines that the pharmacist has clinically checked and has authorised to be handed out in their absence.

5.5 With regard to hospital aseptic facilities, these previously had to be overseen by a registered pharmacist. The changes will allow suitably qualified and experienced registered pharmacy technicians to take primary responsibility for the preparation and assembly of medicinal products in these specialised pharmacy services. This will enable pharmacists to take on more clinical roles across multi-disciplinary teams in hospitals and widen the pool of people that can take charge of these facilities. The instrument requires a relevant service (a hospital aseptic facility) to be overseen by a chief pharmacist, who has a statutory responsibility in respect of the safe and effective running of the pharmacy services in a hospital. This is a key element of the governance that underpins the provisions. Hospital aseptic facilities without a chief pharmacist will not be able to rely on the flexibilities the instrument provides.

6. Legislative and Legal Context

How has the law changed?

6.1 The changes have been made by a combination of amendments to the Medicines Act 1968 and the Human Medicines Regulations 2012 (the HMR).

6.2 Currently section 10(1) of the Medicines Act 1968 and Regulations 4 and 220 of the HMR enables the preparation, assembly, dispensing, sale and supply of pharmacy and prescription only medicines by a pharmacist, or under the supervision of a pharmacist - in specified settings. To enable greater delegation by pharmacists to pharmacy technicians, we are proposing to introduce a new, additional method of delegation termed 'authorisation', into pharmacy practice.

6.3 Inserting section 10(1A) and section 10A into the Medicines Act 1968 and Regulation 220A into the HMR, enables pharmacists to authorise a registered pharmacy technician to either carry out tasks relating to the preparation, assembly, dispensing and sale or supply of medicines - or with the authorisation of the pharmacist - to supervise others to carry out these tasks. As pharmacy technicians are currently not a regulated profession in Northern Ireland, this provision will only apply in Great Britain. Our aim is for this legislation to apply in Northern Ireland once this is possible.

6.4 Inserting Regulation 220B into the HMR allows pharmacists to authorise any member of the pharmacy team to hand out dispensed prescriptions (which have been checked for clinical appropriateness and accuracy) in the pharmacist's absence. This provision will apply in the United Kingdom.

6.5 Inserting Regulation 4A into the HMR permits registered pharmacy technicians to supervise the preparation, assembly and dispensing of medicines in hospital aseptic facilities. This would enable suitably qualified and experienced pharmacy technicians to be responsible for a hospital aseptic facility without having to act under the supervision (or authorisation) of a pharmacist. These amendments do not change that medicines supplied to the hospital aseptic facility for preparation, assembly or dispensing must generally be lawfully on the market in the UK and must not be modified by the preparation, assembly or dispensing to such an extent that a "new" medicinal product is created by that process (noting that there are exceptions for what are known as magistral or officinal formula products). As pharmacy technicians are currently not a regulated profession in Northern Ireland, this provision will only apply in Great Britain. Our aim is for this legislation to apply in Northern Ireland once this is possible.

6.6 Article 48 of the Pharmacy Order 2010 (standards of conduct, ethics and performance) is amended to reflect that professional standards and responsibilities of a registered pharmacist should reflect expectations of registered pharmacists giving an authorisation. Similar changes are made to the Pharmacy (Northern Ireland) Order 1976.

6.7 The instrument makes a number of consequential changes to The Medicines for Human Use (Clinical Trials) Regulations 2004; the HMR; Regulation 167 (concerning special medicinal products), Regulation 217B and 217C (both concerning original pack dispensing), and other minor changes. Consequential amendments are also made to the Misuse of Drugs (Safe Custody) Regulations 1973 and the Misuse of Drugs Regulations 2001 to reflect that medicines (including controlled drugs) can now be supervised by a registered pharmacist or registered pharmacy technician at or from a registered pharmacy premises or other pharmacy setting covered by this Order. For the sake of clarity, Regulations 6(5), 6(6) and 6(7)(f) of the Misuse of Drugs Regulations 2001 already allow any person, for example, a pharmacy counter assistant or other member of pharmacy staff, to convey a controlled drug to a person who may lawfully have that drug in their possession, such as a patient with a valid prescription from a doctor, a pharmacist or other lawful prescriber. Therefore, pharmacy staff

acting under the supervision of a pharmacist, or in future acting under the supervision of a pharmacy technician, may handle controlled drugs pursuant to the lawful supply of these medicines.

6.8 Separately, changes will also be made to the Value Added Tax Act 1994 to maintain that medicines dispensed in a pharmacy are zero-rated – regardless of whether the medicine has been dispensed by or under the supervision of a pharmacist or pharmacy technician. This will ensure there are no financial barriers for NHS pharmacy contractors implementing these changes. The intention is that all consequential changes will come into force at the same time this Order enters into force.

Any legal issues

6.9 Legal issues which may arise relate to the lack of an explicit definition for key terms used in legislation.

6.10 'Supervision' is not defined in legislation, and as there is conflicting case law in this area, it is recognised that there is some disagreement as to what the law currently requires in terms of 'supervision'. As 'authorisation' is not being defined in legislation, there is a risk a similar issue could occur with this term too. However, to mitigate this risk, a transition period will be provided before the law comes into force. This period of transition will allow the pharmacy regulators and professional bodies to define what professional good practice means in-terms of authorisation, before it comes into practice.

6.11 At consultation stage, DHSC set out a detailed summary of the relevant case law and professional guidance applicable to determining what 'supervision' means in practice. This aimed to give clarity to the sector and profession. DHSC and the Devolved Governments support the guidance issued by the Royal Pharmaceutical Society of Great Britain - the precursor to the Royal Pharmaceutical Society (RPS) and the General Pharmaceutical Council (GPhC) - RPSGB 2005 Law and Ethics Bulletin[1] and welcome the commitment from the RPS to update this guidance once this instrument enters into force.

Why was this approach taken to change the law?

6.12 This approach was taken as we wanted to allow greater delegation by pharmacists to appropriately trained members of staff, and we also wanted to ensure that a registered pharmacy professional is always responsible for the dispensing of medicines. We have chosen to be more enabling when it comes to allowing pharmacy technicians to supervise hospital aseptic facilities to reflect how the workforce has developed in this area.

7. Consultation

Summary of consultation outcome and methodology

7.1 Following pre-consultation engagement with the sector and profession, a UK-wide consultation ran for 12 weeks between 7 December 2023 and 29 February 2024. To encourage responses to the consultation, officials from DHSC, Devolved Governments and the NHS supported a number of engagement events during the

[1] A printed version is available on request from the Royal Pharmaceutical Society of Great Britain, 66 East Smithfield, London E1W 1AW and an electronic copy is available upon request from the RPS at: library@rpharms.com

consultation period. The aim was to ensure that stakeholders understood the proposals fully and had an opportunity to raise questions and concerns for clarification.

7.2 In total, we received 5,042 responses to our online consultation and 16 written submissions. This included responses from pharmacy businesses, national community pharmacy representative bodies, NHS Trusts and providers, professional leadership bodies and individual pharmacy professionals.

7.3 The majority of organisations and pharmacy technicians who responded to the consultation welcomed the proposed changes, but the majority of pharmacists did not. We accept that many pharmacists are cautious in accepting the changes until they can see the detail of how they will be implemented. In response to the main concerns raised at consultation, we are proposing amending the Pharmacy Order 2010 and Pharmacy (Northern Ireland) Order 1976 concerning professional standards for pharmacy professionals. These proposed changes are designed to address two of the main concerns raised at consultation – documentation when an authorisation is given orally and how can we manage the risks of a Superintendent Pharmacist (a senior pharmacist responsible for all pharmacy premises within a corporate body) overriding the Responsible Pharmacist (the pharmacist responsible for the day to day running of an individual pharmacy premise) and authorising remotely across multiple pharmacies. The proposed changes will make clear that the regulators, when setting standards of conduct, ethics and performance, could include descriptions of the professional responsibilities that pharmacists are to have for documenting authorisations given orally and describe in more detail who is professionally appropriate to authorise.

7.4 Out of the three proposals put forward as part of this consultation, it is the third proposal; to allow pharmacy technicians to supervise hospital aseptic facilities on the same basis as a pharmacist currently does, that has split views, of which most were amongst stakeholders working in aseptic services. To address these concerns we have conducted post consultation engagement to better understand the views of these groups. Our understanding is that these groups now support the overall objectives of the proposed legislative changes, and we will consider the recommendations they have made to implement these proposals safely.

7.5 The subject matter of the Medicines Act 1968 and the HMR are reserved to the UK government as regards Wales and Scotland, but devolved as regards Northern Ireland. So, although these proposals are supported by the UK Government and the Devolved Governments, the proposed changes are, formally, matters for the Secretary of State for Health and Social Care, in relation to England, Scotland and Wales, and the Department of Health in Northern Ireland in relation to Northern Ireland. However, this statutory instrument is made under powers in section 60 of the Health Act 1999 which provides powers for the Privy Council to make changes to the professional regulatory landscape through secondary legislation across the UK.

7.6 The consultation response has been agreed with the Departments of Health in Scotland, Wales and Northern Ireland and the Chief Pharmaceutical Officers for each nation.

7.7 The Government response to the consultation has been laid before Parliament pursuant to paragraph 9(2) of schedule 3 to the Health Act 1999, and published on the www.gov.uk/government/consultations/pharmacy-supervision website.

8. Applicable Guidance

8.1 The consultation was the first phase of this work, which will be followed by separate consultations by the pharmacy regulators on regulatory standards for the roles of the Responsible Pharmacist and Superintendent Pharmacist, and rules (GPhC) and regulations (PSNI) to replace the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008, concerning the rules around absence of the responsible pharmacist, record keeping etc. The GPhC have already consulted on and issued standards for the role of the Chief Pharmacist – a senior pharmacist responsible for all pharmacy services, usually in a hospital or settings such as care homes, some Integrated Care Boards (ICBs), ambulance trusts, prisons, and other places where people are lawfully detained.

8.2 This will be supported by guidance on practice matters by the professional leadership bodies to be implemented ahead of the provisions entering into force.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the www.legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

9.2 The impact on business, charities or voluntary bodies is zero. The legislation is permissive and therefore has no direct impact on businesses. Where businesses choose to use the new flexibilities made available in this legislation, the impact is expected to have a net positive benefit. The range of potential costs include staff training, administration costs of reviewing and updating standard operating procedures and pharmacy protocols, and higher staff wages to reflect additional roles and responsibilities of pharmacy technicians. Benefits may include releasing pharmacist time to deliver more clinical services, better use of skill mix in pharmacy teams, greater flexibility in how they manage dispensing of medicines and deploy staff, and better patient/public experience when accessing pharmacy services. Further detail is available in the Impact Assessment.

9.3 The legislation does not impact small or micro businesses.

9.4 The legislation does not provide an exemption for small or micro businesses (employing up to 50 people), as the provisions are enabling and not mandatory, therefore the provisions will have no impact if businesses choose not to implement any changes to how they practice or dispense medicines. Where small or micro businesses choose to implement the changes, the same impacts can be expected as those set out above. It is therefore not appropriate to exempt small and micro businesses from the requirements of these regulations, and such businesses should be free to choose whether to adopt changes to their practice if they are beneficial to the business and their patients.

9.5 The impact on the public sector is the expected increased availability of pharmacist time, freeing them to provide additional advice and NHS clinical services to patients and relieve other areas of the NHS. The provisions are also expected to improve patient satisfaction with the process of accessing medicines on the NHS, due to reduced delays and an increase in the workforce available to fill vacancies in NHS hospital aseptic facilities.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The DHSC 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.

10.2 The instrument does not include a statutory review provision and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015 the Minister of State for Care, 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".

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 The Minister of State for Care has made the following statement regarding Human Rights:

"In my view, the provisions of The Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2025 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").