EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENTS RELATING TO HUB AND SPOKE DISPENSING ETC.) REGULATIONS 2025

2025 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 His Majesty.

2. Declaration

2.1 Stephen Kinnock, The Minister of State for Care at DHSC, can confirm that this Explanatory Memorandum meets the required standard.

2.2 Alette Addison, Deputy Director for Pharmacy, Eye Care and Controlled Drugs at DHSC, can confirm that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Inna Kochetkova at DHSC, 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 is essentially about the sharing of aspects of the dispensing of prescriptions for medicines for human use, with a view either to retail sales or to what are known as supplies in circumstances corresponding to retail sale (generally, NHS supplies in community settings). Dispensing covers a number of processes. Within "hub and spoke" dispensing, multiple "spoke" pharmacies receive prescriptions and a single "hub" pharmacy carries out some aspects and probably the more routine aspects of the dispensing of those prescriptions on their behalf, potentially using automation. This division of activities was only possible prior to this instrument between pharmacies within the same retail pharmacy business. The legislative amendments enable the use of hub and spoke arrangements between different retail pharmacy businesses and between a hub pharmacy and NHS dispensing doctors (who can only act as a spoke in hub and spoke arrangements).

4.2 This instrument amends the Human Medicines Regulations 2012 (HMRs) which govern the arrangements throughout the United Kingdom for the licensing, manufacture, marketing, wholesale dealing and the sale and supply of human medicines. It also amends the Medicines Act 1968 (MA 1968), which amongst other things, contains provisions about the registration of premises of retail pharmacy businesses.

4.3 The changes to this legislation go beyond simply removing the barrier that currently limits hub and spoke arrangements to pharmacies within the same legal entity. They also set conditions for the newly permitted arrangements and establish a framework for the sharing of patient information between the hub and the spoke.

Where does the legislation extend to, and apply?

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

4.5 The territorial application of this instrument (that is, where the instrument produces a practical effect) is the United Kingdom.

5. Policy Context

What is being done and why?

5.1 Previously it has only been possible for retail pharmacies that belong to the same legal entity to operate using a hub and spoke arrangements because supplies between two retail pharmacies that were part of different businesses would ordinarily be considered wholesale dealing. As a result, the efficiency benefits of hub and spoke dispensing could not be realised by retail pharmacy businesses that did not operate their own hub, e.g. independent pharmacies or small chains – because hub operations are only likely to be economically viable on a large scale – or dispensing doctors. Removing the legal restriction to outsourcing aspects of dispensing therefore aims to contribute to a levelling of the playing field in the provision of community pharmaceutical services.

5.2 The policy objective is also to enhance dispensing efficiency, in particular in the provision of NHS pharmaceutical services, and free up time for dispensing staff at the spoke to provide more patient-facing services and so better support patients and other parts of the NHS which are under pressure. For example, if pharmacists in community pharmacies have more time to provide clinical services and advice on medication, this could have the effect of freeing up more GP appointments. This complements other strands of policy development that are designed to maximise the use of skill mix in pharmacy teams.

What was the previous policy, how is this different?

5.3 Previously, hub and spoke arrangements between retail pharmacies could only by operated between pharmacies within the same retail pharmacy businesses – and could not operate between NHS GP practices and a hub pharmacy. The amendments will enable the use of hub and spoke arrangements between hub pharmacies and spokes that are either pharmacies owned by different businesses or NHS dispensing doctors, provided medicines are returned to the spoke for final supply. This is made subject to conditions – for example, written arrangements must be in place between the hub and spoke to give a comprehensive statement detailing their responsibilities, and notices about the arrangements must be displayed, in order to inform patients. For further detail of the changes to ensure safe and effective implementation of the policy, see section 6.5 to 6.7.

6. Legislative and Legal Context

How has the law changed?

6.1 The changes have been made by a combination of amendments to the MA 1968 and the HMRs.

The amendments to be made to the MA 1968:

6.2 Section 10 of the MA 1968 enables, amongst other matters, registered pharmacies (that is, pharmacies that do retail sales) to undertake the activities associated with the dispensing of medicines without the need for a manufacturer's licence. Some of those

activities are known as "assembly", which may be as simple as affixing a dispensing label to a patient pack or cover more complex operations such as putting medicines in a new box or a monitored dosage system. The amendment to section 10 removes the restriction that a medicine undergoing any of the processes known as assembly at a registered pharmacy must be sold or supplied by that pharmacy or another registered pharmacy forming part of the same legal entity, if the assembling activities are to be covered by the section 10 exemption.

6.3 Transactions between registered pharmacies that are part of different legal entities, or between registered pharmacies and NHS dispensing doctors would, prior to this instrument, have been considered wholesaling. However, rather than update the definitions of "wholesale dealing" and "retail sale" in section 131 of the MA 1968, these have been removed, and the definitions of those terms going forward will be of those found in the HMRs.

The amendments to be made to the HMRs:

6.4 Essentially, the changes are to ensure that hub and spoke dispensing across different legal entities as described above is properly integrated into the wider provisions of the HMRs and the MA 1968, some conditions are attached to ensure transparency and clarity with regard to hub and spoke operations, and some data sharing issues are properly addressed.

6.5 Written arrangements must be in place between the hub and the spoke which give a comprehensive statement detailing the responsibilities of the hub and the spoke. When medicines are dispensed, a dispensing label is ordinarily affixed with some important information for the patient. If the label is simply affixed to a patient pack (the original form in which the medicine is supplied by the manufacturer) the requirements for the dispensing label are set out in Schedule 25 to the HMRs, and if the medicines are put into different packaging, in Schedule 26 to the HMRs. This instrument provides that it is the spoke's name and address must be on the dispensing label and the final decisions relating to the particulars to be included, for example the directions for use for the medicine, are to be taken, if the spoke is a pharmacy, by a pharmacist at the spoke (NHS dispensing doctors at the spoke will also carry ultimate responsibility for the content of a dispensing label, but it is managed differently). The outcome of this particular change is that it will ensure that the spoke retains responsibility for the final supply to patients and remains the point of contact for patients' queries about their dispensed medicines.

6.6 A further requirement is that the spoke will be required to conspicuously display a notice at their premises detailing the names and addresses of any hub pharmacy that they have entered into arrangements with, alongside a brief statement of the general effect of those arrangements. Any pharmacies or dispensing doctors that dispense via an internet service and utilise hub and spoke will have to include this notice in the pharmacy's or the practice's internet presence (for example, on their website or their app). These arrangements for accountability, governance and transparency of information are key to delivering high standards of patient safety and so these requirements underpin the proposals.

6.7 A new information gateway (as a new regulation 222B) has been created for the hub and spoke arrangements. This will make it clear that the sharing of patient data between the hub and the spoke which is necessary for these purposes will be seen as compliant with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018 (DPA), provided that the hub and the spoke comply with the requirements of both the new legislation and the duties of confidentiality that the

health care professionals and other staff supporting hub and spoke arrangements owe – in the latter case, the staff's confidentiality duties, which parallel the professional obligations of health care professionals, are specifically created by this instrument. The information gateway also provides a sanction in that, should the hub or spoke fail to comply with the new legislation - or someone at the hub or spoke breaches their duty of confidentiality - any related handling of data will be outside of the information gateway and therefore could be subject to regulatory action by the Information Commissioner's Office (ICO).

6.8 The opportunity has also been taken to amend references in the HMRs to the sale or supply of medicines "at" or "on" pharmacy premises; they are changed to "at or from pharmacy premises". This amendment brings the HMRs into line with the MA 1968 in clarifying how and where transactions may take place.

Any legal issues

6.9 A relatively straightforward change in terms of policy has necessitated a relatively complex set of changes to the legislation that underpins the regulatory framework for the supply of medicines in the UK. This is reflective of the highly technical nature of medicines regulation and the importance of ensuring that the appropriate governance is in place for their supply.

Why was this approach taken to change the law?

6.10 There were a number of choices to be made about how to implement the hub and spoke arrangements. These choices included allowing both what is known as model 1 (spoke sends order to hub – hub sends medicines to spoke – spoke supplies medicines to patient) and what is known as model 2 (spoke sends order to hub – hub supplies medicines to patient) or just one of these arrangements. Other options included mandating the content of the arrangements between the hub and spoke in a detailed manner or allowing flexibility on content, requiring a notice to be displayed to inform patients or some other method to ensure patients are informed, mandating which party should be named on the label of the medicine or both, allowing dispensing doctors to form a spoke or not and allowing the spoke to supply medicinal product to the hub or not. The response to the consultation published on 13 May 2024 discusses the evidence received from the consultation and provide a justification for the choice made about how to implement hub and spoke arrangements on each issue. Subsequently and following further conversations with the devolved administrations and pharmacy stakeholders, the decision was made to only implement what is known model 1 hub and spoke dispensing at this stage, not model 2, and instead of providing a choice for the two parties to agree whose details would appear on the dispensing label, to mandate that the spoke's details must be on the label. For hub and spoke arrangements between different legal entities to be permitted at all, there was no alternative to some legislative change.

7. Consultation

Summary of consultation outcome and methodology

7.1 131 Responses to our online questionnaire were received from 71 individuals and 60 interested organisations, which included 22 pharmacy businesses across the range from independents to large multiples, membership organisations, national community pharmacy representative bodies, pharmaceutical wholesalers, professional advisory bodies and regulators.

7.2 A further stakeholder engagement workshop was held on 6 December 2022 to provide detailed responses on the labelling of medicines and spoke to hub supply. In October 2023, 2 further meetings were held, each with one external stakeholder who had offered to provide information relevant to the impact assessment.

7.3 Overall, the consultation evidence demonstrated agreement with the majority of the hub and spoke proposals, more mixed support on a few (labelling and spoke to hub transfer of prepared or assembled medicine) and some concerns (about model 2, competition, market entry, data protection). To address these concerns, as is noted above, the decision was made to only enable model 1 hub and spoke arrangements at this stage and revisit model 2 once model 1 arrangements have been established.

7.4 The consultation response that was published in May 2024 and the revised proposals for the regulatory changes that are now being put forward have been agreed with the Department of Health in Northern Ireland, who are co-signatories to the legislation.

7.5 The regulation of medicines is a reserved matter as regards England and Wales and Scotland and a devolved matter as regards Northern Ireland. The legislative amendments aim to enable the same opportunities for hub and spoke provision across the whole of the Union. However, the terms and conditions of NHS pharmaceutical services are devolved to each of the devolved administrations so each administration will need to consider the implications of the policy change for their NHS commissioned services separately. DHSC officials have engaged at official level with the devolved administrations, mainly through their Chief Pharmaceutical Officers, regarding the proposed legislative changes, to ensure that they are happy with the consultation response.

7.6 The ICO has been consulted, in March 2023, in accordance with Article 36(4) of the UK GDPR. It raised no issues.

8. Applicable Guidance

8.1 Guidance for the implementation of the hub and spoke arrangements may be provided at the next stage in the process, when it is determined by each administration how these arrangements will work within their relevant NHS pharmaceutical services, which is likely to require further legislation. No guidance is contemplated specifically on this instrument.

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 legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

9.2 The impact on business, charities or voluntary bodies is dependent on whether they choose to adopt a hub and spoke arrangements under the new enabling legislation. The range of potential impacts include the set up costs of hub pharmacies; operational costs of hub pharmacies; set up costs for spoke pharmacies including changes to IT systems, new training, dispensing process redesign and new data sharing arrangements across different legal entities, and calmer work environments. Further detail is available in the Impact Assessment.

9.3 The legislation has the potential to impact small or micro businesses as it gives them the option to adopt the flexibilities allowed by the enabling legislative amendments.

9.4 The amendments are enabling and not mandatory, and therefore will have no impact on small or micro businesses (employing up to 50 people) if they do not choose to adopt hub and spoke arrangements. We assess the proposal will only be taken up where it would generate net benefits and so is expected to have a net zero to net benefit impact on SMEs. Smaller businesses are expected to benefit from the proposals, as, under current arrangements, they are less likely to be able to have the economies of scale required to benefit from automation within its own business. By removing the legal barrier to the use of hub and spoke arrangements across different legal entities, this would enable smaller pharmacies to begin to take advantage of these technologies.

9.5 The impact on the public sector is the expected increased availability of pharmacist time at the spoke pharmacy, freeing them to provide additional advice and NHS clinical services to patients and relieve other areas of the NHS.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 This instrument is subject to the reporting requirements in section 46 of the Medicines and Medical Devices Act 2021, which requires a review every 2 years of Regulations made under specified enabling provisions in the Act.

10.2 In line with recommendations by the Competition and Markets Authority (CMA), the Department commits to engaging with stakeholders to review the impact on competition once any hub and spoke market is sufficiently established, to assess if action is needed to alleviate any barriers to the development of a dynamic and competitive hub market.

10.3 The instrument does not include a statutory review clause and, in line with the requirements of the Small Business, Enterprise and Employment Act 2015, Minister Kinnock has made the following statement:

"It is not appropriate in the circumstances to make provision for review in this instrument. This is because there is already a requirement in section 46 of the Medicines and Medical Devices Act 2021 to review the operation of these Regulations every 24 months".

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 at DHSC has made the following statement regarding Human Rights:

"In my view, the provisions of the Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.) Regulations 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”).