

EXPLANATORY MEMORANDUM TO

THE HUMAN MEDICINES (AMENDMENTS RELATING TO REGISTERED DENTAL HYGIENISTS, REGISTERED DENTAL THERAPISTS AND REGISTERED PHARMACY TECHNICIANS) REGULATIONS 2024

2024 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.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Declaration

- 2.1 The Rt Hon Andrea Leadsom, Parliamentary Under Secretary of State (Minister for Public Health, Start for Life and Primary Care) at the Department of Health and Social Care confirms that this Explanatory Memorandum meets the required standard.
- 2.2 Helen Lovell and Kathryn Glover, Deputy Directors for Medicines Regulation and Prescribing, at the Department of Health and Social Care confirm that this Explanatory Memorandum meets the required standard.

3. Contact

- 3.1 Cicely Groom at the Department of Health and Social Care email: medicines.mechanisms@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?

Relating to registered dental therapists and registered dental hygienists:

- 4.1 This instrument makes amendments to the Human Medicines Regulations 2012 (“HMRs 2012”) to allow dental hygienists and dental therapists to supply and administer specified prescription only medicines, ‘pharmacy’ or ‘general sales list’ medicines in the practitioner’s scope of practice under an exemption from the requirement to obtain a prescription.
- 4.2 This will support dental hygienists and dental therapists in providing the right care to patients to reduce unnecessary delays where it is safe and appropriate to do so. It will also improve the use of skill mix in NHS dentistry to ensure the full dental team can be utilised to deliver care to patients, which is an important element in improving access to NHS dentistry. The job satisfaction of these professionals should also be improved by enabling them to work to the full scope of their practice.

Relating to registered pharmacy technicians:

- 4.3 This instrument amends the HMRs 2012 to enable registered pharmacy technicians to supply and/or administer medicines under Patient Group Directions (PGDs).

- 4.4 *Note: A PGD is a set of written instructions which allows healthcare professionals (specified in the HMRs) to supply and administer specific medicines to pre-defined groups of patients without the need for a prescription to be obtained. PGDs can be used in limited situations that present a clear advantage to patient care, without compromising on patient safety, and where there are clear governance arrangements and accountability procedures in place.*
- 4.5 This will enable registered pharmacy technicians to use PGDs across England, Wales and Scotland in any setting including the NHS, independent and voluntary sectors. They will be able to provide direct care to their patients, freeing up capacity in other parts of the healthcare system by supporting community pharmacy to provide more NHS clinical services. The job satisfaction of these professionals should also be improved by enabling them to work to the full scope of their practice.
- 4.6 The role “pharmacy technician” in Northern Ireland is not currently a registered healthcare profession. These amendments to the HMRs 2012 will not enable pharmacy technicians in Northern Ireland to use PGDs. However, once pharmacy technicians in Northern Ireland become a registered healthcare profession, a further amendment to the HMRs 2012 may be made to permit this.

Where does the legislation extend to, and apply?

- 4.7 The extent of this instrument (that is, the jurisdiction(s) which the instrument forms part of the law of) is UK-wide.
- 4.8 The territorial application of this instrument (that is, where the instrument produces a practical effect) is UK-wide.
- 4.9 The role “pharmacy technician” in Northern Ireland is not a registered healthcare profession, so amendments to the HMRs 2012 enabling registered pharmacy technicians in Northern Ireland to use PGDs will have no effect in that jurisdiction.
- 4.10 Medicines regulation is a reserved matter (to the UK Parliament) in relation to Scotland and Wales. It is a transferred matter in Northern Ireland, which is why changes to the UK-wide HMRs 2012 in so far as they affect Northern Ireland are made under the Medicines and Medical Devices Act 2021 (MMDA) jointly by the Secretary of State and Department of Health in Northern Ireland.

5. Policy Context

Relating to registered dental therapists and registered dental hygienists

What is being done and why?

- 5.1 NHS England (NHSE) identified, through engagement with stakeholders, that PGDs have been difficult to develop in the dental primary care setting. This is primarily due to most dental hygienists and dental therapists working with dentists who are not directly employed in the NHS, but under contract to deliver a dental service. This means there is no readily accessible governance framework within which to develop and implement PGDs. Additionally, the national guidance on the writing and signing of PGDs requires the input of a senior pharmacist. Most dental services do not have access to this expertise.
- 5.2 Exemptions within the HMRs 2012 allow certain medicines, or classes of medicine (for example prescription-only medicines), listed in legislation to be lawfully sold, supplied and/or administered to patients by specific health professional groups without using a prescription, PGD or Patient Specific Direction (PSD).

- 5.3 *Note: A PSD is a written instruction from an appropriate practitioner (who is an independent prescriber) to administer a medicine to a named patient/s. The practitioner, such as a dentist, must have assessed the patient on an individual basis before prescribing the medicine. The use of PSDs has limitations as it requires direct input from a prescriber for each individual patient for a single course of treatment which can lead to delays to patient care.*
- 5.4 Patients who receive oral health treatment from dental hygienists and dental therapists through the proposed exemptions would be able to receive all the treatment they need without additional appointments or having to see another dental professional to receive the associated medicines.
- 5.5 These provisions will enable registered dental hygienists and registered dental therapists working under the new exemptions within the HMRs 2012 to supply or administer specific medicines within the limitations of that exemption in the course of their professional practice. This will help reduce delays in treatment, as dental hygienists and dental therapists will be able to supply and administer certain medicines without needing to use a PGD, or a prescription or a PSD from a dentist.
- 5.6 Dental hygienists and dental therapists who are qualified to use the specified medicines must only use the exemptions where they have the skills and competencies to do so. Some may need additional training.
- 5.7 The specified medicines include the following prescription only medicines:

Local or topical anaesthetics:

- lidocaine 2% with 1:80,000 adrenaline
- articaine hydrochloride 4% with 1:100,000 adrenaline
- articaine hydrochloride 4% with 1:200,000 adrenaline
- 3% mepivacaine hydrochloride
- 3% prilocaine with 0.54 microgram/ml felypressin
- 2.5%/2.5% lidocaine and prilocaine (periodontal gel)
- 15% lidocaine, 0.15% cetrimide oromucosal spray

Fluoride – either professionally applied, or used as a toothpaste at home:

- sodium fluoride varnish, 50mg/ml (2.26%) dental suspension (containing 22,600ppm fluoride)
- sodium fluoride 0.619% (2,800ppm fluoride) dental paste
- sodium fluoride 1.1% (5,000ppm fluoride) dental paste

Locally applied antibiotic gel:

- minocycline 2% periodontal gel

Locally applied antifungal:

- nystatin oral suspension

- 5.8 In addition, registered dental hygienists and registered dental therapists will be able to supply all general sales list and pharmacy medicines licensed in the UK to their

patients that are within the scope of their professional practice because of these amendments.

What was the previous policy, how is this different?

- 5.9 Dental hygienists and dental therapists currently must either ask dentists to assess the patient and write a PSD or use a PGD, if one is available, before they can supply or administer medicines.
- 5.10 PGDs (as explained in 4.4) are often not suitable for use in dental practices due to the longer process that comes with them. Many dental hygienists and dental therapists currently must ask dentists to assess the patient and write a PSD where necessary to continue treatment. This can be inefficient, as a dental hygienist or dental therapist can identify a need for the medicine and is qualified to supply or administer it. It can lead to unnecessary delays and means a patient needs to be handed over to a dentist, then handed back to the dental hygienist or dental therapist.
- 5.11 Under the new policy, registered dental hygienists and registered dental therapists will be able to supply and administer the specified prescription only medicines, pharmacy, or general sales list medicines in the practitioner's scope of practice, under the exemption without the use of a PSD or PGD, or obtaining a prescription.

Relating to registered pharmacy technicians:

What is being done and why?

- 5.12 Pharmacy technicians are a regulated profession. They work under the supervision of the pharmacist to ensure the safe running of the pharmacy and make sure patients get the most from their medicines, focusing on the preparation of medicines and other healthcare products, and increasingly also play an active role in offering support and guidance to patients and the public. To qualify, pharmacy technicians need to complete a General Pharmaceutical Council (GPhC)-approved integrated competency and knowledge-based qualification or course.
- 5.13 Pharmacy technicians work in various settings across primary and secondary care. They work in a wide range of different places including community pharmacies, GP practices, hospitals, care homes, community services, prisons, the armed forces and the pharmaceutical industry. Their role in those settings will vary accordingly.
- 5.14 For comparison, a pharmacy can't operate without a responsible pharmacist. That individual is responsible for the safe and effective running of the pharmacy. Pharmacists have overall responsibility for the dispensing of medicines that takes place in their pharmacy. They can train to prescribe medication. They instruct doctors on what medicines and dosages to give patients.
- 5.15 Pharmacy technicians are not currently included in the list of registered healthcare professionals authorised to supply and/or administer medicines under a PGD, despite having acquired the necessary skills and knowledge within their role as a registered healthcare professional.
- 5.16 The use of PGDs by pharmacy technicians will make it easier for patients to get the medicines they need when they need them, whilst maintaining public safety. This will avoid the requirement for patients to see additional health professionals just to receive medicines, where it is safe and appropriate to do so, thereby facilitating timely access to medicines, improving patient care and patient experience.
- 5.17 The policy contributes to the ambition of the NHS to maximise the use of the skill-mix in pharmacy teams, enabling them to meet more of the health needs of the local

population they serve. By utilising the skills of the whole pharmacy team, pharmacists in community pharmacy will be able to deliver more patient-facing clinical services, improving access to patient care, and freeing up capacity in the wider NHS. This will also enable registered pharmacy technicians to maximise the contribution they make within multi-professional teams through more effective use of their unique skills and expertise.

- 5.18 With the continuing expansion of more than 4,500 registered pharmacy technicians working in primary care, the opportunities for patient-centred service redesign are critical to enable improved access to healthcare, address health inequalities and reduce burden on general practice. The changes will also enable better career prospects for pharmacy technicians, particularly in community pharmacy.

What was the previous policy, how is this different?

- 5.19 Prior to this legislative change, the only mechanism by which registered pharmacy technicians could supply and administer medicines was where they were authorised to do so by a PSD.
- 5.20 This medicines mechanism, however, does not fully utilise the skills and knowledge of registered pharmacy technicians who could, as registered healthcare professionals, use their education and training to supply and administer medicines safely under a PGD.
- 5.21 The changes to the law will enable pharmacy technicians to use PGDs in general. Individual PGDs will set out whether pharmacy technicians will be allowed to supply or administer medicines under those PGDs and what medicines they are allowed to supply and administer. For example, flu and Covid-19 vaccinations are administered under PGDs and pharmacy technicians could be included in those.
- 5.22 A further example is the contraception service in community pharmacy which uses PGDs to supply patients with oral contraception. NHS England, as the commissioner, may want to expand this service to also include pharmacy technicians on the PGDs. In pharmacy settings this will enable better use of the skill mix in the pharmacy and free up pharmacists to provide other clinical services.
- 5.23 The use of PGDs will make it easier for patients to access the medicines and services they need in a timely and effective manner, avoiding the risks associated with delayed care, and improving patient outcomes.

6. Legislative and Legal Context

How has the law changed?

- 6.1 The HMRs 2012 set out a comprehensive regime for the authorisation of medicinal products, including the sale, supply and administration of medicines and were made under section 2(2) of the European Communities Act 1972. The regulations 214, 220 and 221 of the HMRs 2012 include prohibitions to the supply and administration of certain medicines without prescription from an appropriate practitioner or restriction on how they may otherwise be supplied. Further provisions which allow certain individuals, including registered healthcare professionals, to sell, supply and/or administer medicines to patients in reliance on exemptions to the requirement to obtain a prescription from an appropriate practitioner are contained in Part 12 Chapter 3 when read with the relevant schedule to the HMRs.
- 6.2 Regulations 230 to 234 (inclusive) and schedule 16 to the HMRs contain an exemption which enables registered health professionals listed in schedule 16 to use

PGDs to lawfully sell, supply and/or administer medicines to patients without obtaining a prescription.

- 6.3 Regulation 235 and schedule 17 of the HMRs contain exemptions that enable specified individuals, subject to conditions, to lawfully sell, supply and/ or administer specific medicines without the need to obtain a prescription.
- 6.4 The amendments made by this instrument will expand the scope of these exemptions within the HMRs regarding supply and administration of certain medicines. First, the instrument adds registered pharmacy technicians to the registered health professionals listed in schedule 16 enabling them to supply and administer medicines in accordance with PGDs. Secondly, the instrument adds registered dental hygienists and registered dental therapists who are qualified to sell, supply and administer the medicines specified in the instrument to schedule 17.
- 6.5 The MMDA provides enabling powers to make provisions amending or supplementing the “law relating to human medicines”, which includes the HMRs. The MMDA was put in place as a result of the UK’s exit from the European Union.

Why was this approach taken to change the law?

- 6.6 This is the only possible approach to make the necessary changes.

7. Consultation

Regarding registered dental therapists and registered dental hygienists:

Summary of consultation outcome and methodology

- 7.1 In 2020 NHSE held UK-wide public consultations on several proposals to extend medicines responsibilities to additional regulated health professions. This included consulting on enabling dental hygienists and dental therapists to supply and administer a few specific medicines under exemptions. NHSE developed the clinical case for change in consultation with the devolved administrations, professional bodies and colleges, and patient representatives. Most responses to the consultation held by NHSE were supportive and there was strong support for these proposals in the dental care sector.
- 7.2 DHSC and the Department of Health in Northern Ireland issued an additional joint public consultation, “Proposal to enable dental hygienists and dental therapists to supply and administer specific medicines under exemptions”, which was published on GOV.UK and ran for four weeks from 18 August to 15 September 2023.
- 7.3 This additional consultation was necessary under the MMDA. It received 2,744 responses, including from individual members of the public, NHS and health service delivery bodies, and private and non-profit organisations. The feedback was overwhelmingly positive, with 97% of responses agreeing with the proposal.
- 7.4 The consultation response document can be found on the following webpage: [Proposal to enable dental hygienists and dental therapists to supply and administer specific medicines under exemptions: consultation response - GOV.UK](https://www.gov.uk/government/consultations/use-of-exemptions-by-dental-hygienists-and-dental-therapists/outcome/proposal-to-enable-dental-hygienists-and-dental-therapists-to-supply-and-administer-specific-medicines-under-exemptions-consultation-response) (www.gov.uk)¹

¹ <https://www.gov.uk/government/consultations/use-of-exemptions-by-dental-hygienists-and-dental-therapists/outcome/proposal-to-enable-dental-hygienists-and-dental-therapists-to-supply-and-administer-specific-medicines-under-exemptions-consultation-response>

Regarding registered pharmacy technicians:

Summary of consultation outcome and methodology

- 7.5 The Department of Health and Social Care held a joint consultation with the Department of Northern Ireland “Proposal for the use of patient group directions by pharmacy technicians” to seek views on amending the HMRs to enable pharmacy technicians to supply and administer medicines using PGDs.
- 7.6 The consultation was published on GOV.UK and ran for six weeks from 18 August to 29 September 2023. This consultation was necessary under MMDA.
- 7.7 The consultation received 2,267 responses, including from individuals, NHS and health service delivery bodies, and private and not-for-profit organisations. The feedback was overwhelming positive with 84% of respondents agreeing with the proposal.
- 7.8 The consultation response document can be found on the following webpage: [Proposal to enable pharmacy technicians to supply and administer medicines using patient group directions: consultation response - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/consultations/proposal-for-the-use-of-patient-group-directions-by-pharmacy-technicians/outcome/proposal-to-enable-pharmacy-technicians-to-supply-and-administer-medicines-using-patient-group-directions-consultation-response)²

8. Applicable Guidance

- 8.1 Guidance accompanying the legislation will be critical for proper implementation and interpretation of this instrument. Guidance for implementation for this amendment will be provided by the relevant professional bodies ahead of the SI coming into force.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

- 9.1 Two full Impact Assessments are submitted with this memorandum - one detailing the proposals relating to pharmacy technicians and the other detailing the proposals relating to dental therapists and dental hygienists. Both are published alongside the Explanatory Memorandum on the legislation.gov.uk website.

Impact on businesses, charities and voluntary bodies

- 9.2 There is no, or no significant, impact on business, charities, or voluntary bodies.
- 9.3 The legislation does impact small or micro businesses.
- 9.4 No specific action is proposed to minimise regulatory burdens on small businesses. The Government foresees that the introduction of use of exemptions by dental hygienists and dental therapists and the use of PGDs by pharmacy technicians may create a small burden for professionals and dental practices/pharmacies where staff complete the training to be qualified to use the exemptions/PGDs. However, this burden will be outweighed by the increased patient safety and efficiencies gained. The instrument does not mandate use of exemptions/PGDs, and dental practitioners/pharmacy technicians therefore do not have to adopt the practice of using them should they choose not to do so.
- 9.5 There is no, or no significant, impact on the public sector.

² <https://www.gov.uk/government/consultations/proposal-for-the-use-of-patient-group-directions-by-pharmacy-technicians/outcome/proposal-to-enable-pharmacy-technicians-to-supply-and-administer-medicines-using-patient-group-directions-consultation-response>

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

- 10.1 Section 46 of the MMDA requires the Secretary of State to lay a report before Parliament every two years on the operation of regulations made under section 2(1) (and other powers under the Act) with the next reporting period concluding in July 2025. Consequently, 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 Andrea Leadsom 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 This instrument is made under powers in the MMDA. It amends the HMRS, which were made under section 2(2) of the European Communities Act 1972. This instrument is subject to the draft affirmative procedure.

12. European Convention on Human Rights

- 12.1 The Parliamentary Under Secretary of State in the Department of Health and Social Care Andrea Leadsom has made the following statement regarding Human Rights:

“In my view the provisions of the Human Medicines (Amendments relating to registered dental hygienists, registered dental therapists and registered pharmacy technicians) Regulations 2024 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”).