Department of Health & Social Care

Closed consultation

Proposal for the use of patient group directions by pharmacy technicians

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Contents

This publication is available at https://www.gov.uk/government/consultations/proposal-for-the-use-of-patient-group-directions-by-pharmacy-technicians/proposal-for-the-use-of-patient-group-directions-by-pharmacy-technicians

Introduction

This consultation seeks views on the proposal to enable registered pharmacy technicians to supply and administer medicines under a patient group direction (PGD).

It is the ambition of NHS systems across the United Kingdom to maximise the use of the skill mix in pharmacy teams, enabling them to meet more of the health needs of their local populations. By utilising the skills of the whole pharmacy team, pharmacists in community pharmacy will be enabled to deliver more patient-facing clinical services, improving access to care for patients and releasing capacity in the wider NHS. Across other clinical settings this proposal will enable registered pharmacy technicians to maximise the contribution they make within multi-professional teams through more effective use of their unique skills and expertise.

This proposal is supported by all 4 nations across the UK where the future ambitions for the pharmacy technician profession are addressed in the documents below:

- in England: supports the delivery of the NHS Long Term Plan (https://www.longtermplan.nhs.uk/), the NHS Long Term Workforce Plan (https://www.england.nhs.uk/publication/nhs-long-term-workforce-plan/) and the Delivery plan for recovering access to primary care (https://www.england.nhs.uk/long-read/delivery-plan-for-recovering-access-to-primary-care-2/)
- in Scotland: supports the future vision for pharmacy in Pharmacy 2030: a professional vision (https://www.rpharms.com/pharmacy2030)
- in Wales: supports the achievement of ambitions set out in Pharmacy: delivering a healthier Wales (https://www.rpharms.com/wales/pharmacy-delivering-a-healthier-wales) and A new prescription (https://www.gov.wales/community-pharmacy-contractual-framework-reform)
- in Northern Ireland: supports the commitment to develop the pharmacy technician profession in the Pharmacy workforce review 2020 (https://www.health-ni.gov.uk/publications/pharmacy-workforce-review-2020) and Introduction of statutory regulation of the pharmacy technician (https://www.health-ni.gov.uk/consultations/introduction-statutory-regulation-pharmacy-technician-workforce-northern-ireland)

A PGD is a written instruction that permits listed healthcare professionals to supply or administer medicines to a pre-defined group of patients. The aim of this proposal is to make it easier for patients to get the medicines they need when they need them, while maintaining public safety. This will avoid the requirement for patients to see additional healthcare 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.

The Secretary of State for Health and Social Care, in relation to England and Wales and Scotland, in conjunction with the Department of Health in Northern Ireland in relation to Northern Ireland (pursuant to Section 45(1) of the Medicines and Medical Devices Act 2021 (https://www.legislation.gov.uk/ukpga/2021/3/enacted)), is seeking views on the proposal to amend the Human Medicines Regulations 2012 (HMRs) (https://www.legislation.gov.uk/uksi/2012/1916/contents/made) to allow registered pharmacy technicians to supply and administer medicines under a PGD.

The amendment will be implemented by a statutory instrument (SI) under enabling powers in the Medicines and Medical Devices Act 2021 (MMD Act). The proposed changes would enable registered pharmacy technicians to use PGDs across England, Wales and Scotland in any setting including the NHS, independent and voluntary sectors. However, these powers do not mean that organisations are required to implement the use of PGDs by registered pharmacy technicians. PGDs should only be used where there is clear benefit for patient care without compromising patient safety and where there are clear governance arrangements and accountability.

Pharmacy technicians in Northern Ireland are not a registered healthcare profession so amendments to the HMRs cannot currently allow 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 may be made so they can also use PGDs.

Proposal to change the Human Medicines Regulations 2012 (HMRs) for registered pharmacy technicians

Patient group directions (PGDs)

A PGD is a written instruction that allows healthcare professionals specified within the HMRs to supply and/or administer a medicine directly to a group of patients with an identified clinical condition. PGDs are not a form of prescribing.

A PGD allows the supply and administration of named medicines in an identified clinical situation, without the need for an appropriate prescriber under the HMRs to provide an individual written prescription. A PGD is a legal mechanism for the administration and/or supply of a medicine. The healthcare professional working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD and should or should not be supplied

or have administered the medicine concerned. The supply and/or administration of medicines under a PGD cannot be delegated - the whole episode of care must be undertaken by the healthcare professional operating under the PGD. A separate PGD is recommended for each different medicine to be supplied or administered.

PGDs are developed by multi-professional groups with extensive expertise, requiring a significant amount of time and resource to develop and authorise. Once implemented, PGDs are subject to ongoing monitoring. The governance involved in the consideration, development, authorisation and maintenance of PGDs ensures the safe and effective supply and administration of medicines by a designated healthcare professional. As set out in schedule 16 of the HMRs, the following list of registered healthcare professionals are permitted to supply and administer medicines under a PGD:

- pharmacists
- registered chiropodists and podiatrists
- registered dental hygienist
- registered dental therapist
- registered dietitians
- registered midwives
- registered nurses
- registered occupational therapists
- registered optometrists
- registered orthoptists
- registered orthotists and prosthetists
- registered paramedics
- registered physiotherapists
- registered radiographers
- registered speech and language therapists

While these healthcare professionals are eligible to use PGDs, it is for local organisations to agree the appropriateness for their use within a clinical service using the national guidelines and local governance to inform the decision.

There are no current plans to amend the Misuse of Drugs Regulations 2001 (https://www.legislation.gov.uk/uksi/2001/3998/contents/made) to enable registered pharmacy technicians to supply and/or administer controlled drugs (https://www.gov.uk/government/publications/controlled-drugs-list--2) in any of the 5 schedules under a PGD.

Use of PGDs by private practitioners

As General Pharmaceutical Council (GPhC) regulated healthcare professionals, pharmacy technicians working in private practice are governed and regulated by the same standards as those working in the NHS, and the standard of care expected is the same. Should PGDs be permitted within the clinical setting, PGDs should be written, authorised and implemented in line with all the relevant national and local governance requirements, and developed according to National Institute of Clinical Excellence (NICE) guidance, Medicines practice guidance (MPG2) (https://www.nice.org.uk/guidance/mpg2). Employers outside the NHS have the same roles and responsibilities as those within the NHS and must implement the same standard of local governance arrangements related to the safe storage, supply and administration of medicines.

In addition, their practice or clinic must also be registered and regulated by one of the following, depending on the location of the practice:

- in England, the Care Quality Commission (CQC) - the independent regulator of health and adult social care service providers in England or the GPhC if it is a registered pharmacy
- in Wales, Healthcare Inspectorate Wales - the independent inspectorate and regulator of healthcare in Wales
- in Northern Ireland, the Regulation and Quality Improvement Authority - responsible for inspecting the availability and quality of health and social care services
- in Scotland, Healthcare Improvement Scotland - responsible for regulating independent healthcare services

Benefits of registered pharmacy technicians being able to supply and administer under PGDs

The only mechanism by which registered pharmacy technicians can currently supply and administer medicines is where they are authorised to do so by a patient specific direction (PSD). A PSD is a written instruction to supply or administer a medicine to a named patient who has been assessed on an individual basis by the authorised prescriber who then prescribes the medicine. The PSD enables a pharmacy technician to administer or supply the medicine to the patient.

This 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. If PGDs were in place, registered pharmacy technicians could administer specific medicines under an appropriate PGD without requiring the intervention of trained prescribers. This would enable pharmacy technicians to take responsibility for their decisions to administer and supply medicines in

accordance with the written PGD. The PGD provides a clear scope of practice with specific education and governance requirements defined by appropriate clinical governance assurance processes.

The use of PGDs for the supply and/or administration of medicines can bring benefits to patients, commissioners and providers. Registered pharmacy technicians can use their medicines expertise to help make every contact count and reduce further health interventions. The proposed use of PGDs will enable patients to access the medicines and services they require in a timely and effective manner, avoiding the risks associated with delayed care, and improving patient outcomes. 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.

All 4 nations of the UK want to further integrate community pharmacy into the NHS. By better utilising the clinical skills of pharmacy teams, community pharmacies will be able to provide more NHS clinical services closer to where people live and become the first contact for managing minor self-limiting illnesses. Within community pharmacy, this proposal will enable registered pharmacy technicians to supply and administer certain medicines directly under a PGD, without the requirement to obtain a PSD from an independent prescribing pharmacist.

This is pertinent as initial education and training reforms will see pharmacists become independent prescribers from the point of registration from 2026 onwards. As part of this reform, registered pharmacy technicians will be required to capitalise on their registered status and post-registration education to deliver a broader range of tasks. This will enable independent prescribing pharmacists to deliver more clinical orientated services, particularly in community pharmacy and general practice settings.

Taken together, independent prescribing pharmacists and the use of PGDs by registered pharmacy technicians could increase the capacity for prescribing, supply and administration of medicines. Within community pharmacies this will provide patients with access to a wider range of clinical services delivered by healthcare professionals with the right skills at the right time, supporting improved patient outcomes. It could also reduce demand in other parts of the healthcare system.

Overall, this proposal increases access to medicines for patients by improving convenience and efficiency of service delivery, and by maximising appropriate use of professionals in the team.

It is for commissioners (national and local) to monitor the use of PGDs, including examples of how they contribute to wider ambitions, such as freeing up other healthcare professionals' time or reducing the pressure elsewhere in the NHS.

Use in clinical practice (scenarios)

The examples below demonstrate the breadth and contributions the profession could support across healthcare sectors to support expansion of service accessibility for patients.

Registered pharmacy technicians administering vaccines

Pharmacy technicians have responded rapidly and professionally to the pandemic and all its challenges. Through late 2020 and early 2021 there was rapid mobilisation of the profession to support the distribution, preparation and administration of the COVID-19 vaccine on NHS sites and other centres.

The experience, skills and knowledge of pharmacy technicians has contributed to the success of the vaccination programme - from receipt, stock management and distribution of the vaccine, to support with preparation of the vaccine prior to administration.

The current legal and governance framework does not allow registered pharmacy technicians to administer vaccines where vaccination centres choose to operate their vaccination programme under a PGD.

Pharmacy technicians have become an integral part of the COVID-19 vaccination roll out and delivery. Pharmacy technicians have been able to administer vaccines where the choice of legal mechanism to support service has been via PSD or national protocol.

There is working experience and evidence of successful implementation of pharmacy technician skills across all parts of the patient's vaccination journey, from receipt of vaccine to administration. The success of the national COVID-19 vaccination roll out and delivery relies on the ability to operate effectively and with 'lean' processes that maximise the skill sets available by the staff engaged in providing the service.

The current model does not allow registered pharmacy technicians to fully participate, as the legal framework excludes them from certain parts of the process (for example, patient consent). This leads to fragmentation in service provision that could be addressed using a PGD that allows registered pharmacy technicians who complete specific PGD training, and are deemed competent, to be involved in the whole process.

Including pharmacy technicians as registered healthcare professionals able to supply and administer medicines under a PGD will result in longer-term benefits for patients. There are clear benefits to be realised from a service provision model that uses a more holistic approach to the patient vaccination journey, both in terms of patient safety and service effectiveness.

The scale of vaccination programmes for both COVID-19 and influenza means that pharmacy technicians have the potential to contribute more to other

immunisation programmes by enabling them to administer vaccines under PGDs. They are well positioned and have demonstrated they have the required skill set and knowledge to support this safely and effectively.

Registered pharmacy technicians administering emergency contraception (EC)

The most recent UK estimates from the National Survey of Sexual Attitudes and Lifestyles (NATSAL) were that 45% of pregnancies were unplanned or ambivalent (Lancet, 2013). This leads to high costs within the NHS, with direct medical costs of £193,200,000 in 2010. It is clear to see the potential cost savings of a programme of preconception care that simultaneously seeks to prevent unwanted pregnancies while improving the planning and preparation of those that are desired. There were 817,515 conceptions in 2020 to women aged 15 to 44 years in England and Wales.

Registered pharmacy technicians in community pharmacy are well positioned to supply emergency contraception (EC). Along with EC PGD competency training, the underpinning knowledge gained in human physiology, pharmacology of medicines and patient consultation skills provides a sound basis to enable appropriate assessment of the presenting patient in terms of:

- suitability and eligibility for a supply (inclusion criteria, concomitant medication and medicines interactions)
- consent
- ability to signpost patients to appropriate services, should they not be eligible
- advice in relation to administration, side effects and risks should the patient decline treatment after counselling

The supply associated with the PGD is defined and there is a standard dose requiring no adjustment or calculation. Including registered pharmacy technicians in EC supply under a PGD gives pharmacies the ability to offer presenting patients a wider range of pharmacy professionals with which to discuss their treatment. This may be preferable in a sensitive situation and could expand the pharmacies capacity to provide a broader range of services.

Registered pharmacy technicians administering oral contraception (OC)

Several contraception services have been commissioned across the UK. For example, in April 2023, the NHS Pharmacy Contraception Service was introduced in England as an advanced service under the Community Pharmacy Contractual Framework (CPCF). The service provides ongoing oral contraception for women, initiated in primary care or sexual health clinics (or equivalent) and is undertaken using PGDs. Similarly, bridging contraception (desogestrel) administered via PGD was introduced in Scotland in November 2021 under the Public Health Service element of the Scottish Contract.

Currently, these services are provided by a pharmacist, although there is scope for registered pharmacy technicians to deliver them if they can demonstrate evidence of competence in the clinical skills and knowledge required to provide the service. This will free up pharmacists' time, which could be used to focus their clinical expertise on treating more complex cases within community pharmacy.

Registered pharmacy technicians in pre-op clinic

The pharmacy technician's role in pre-op clinic includes medicines reconciliation, medication supply, patient counselling and discharge facilitation, often in patients categorised as 'low risk' on specific elective pathways. As part of the multi-professional team pharmacy technicians often:

- complete the patient assessment prior to surgery
- take and confirm medication history
- transcribe inpatient prescription charts ready for inpatient stay
- provide advice and information about medication both pre-op and post-op, including what to stop and start, to minimise risks and optimise outcomes

In all circumstances the pharmacy technician can refer to a pharmacist or clinician. This allows pre-op clinical pharmacists to target their resources towards the management of more complex and/or high-risk patients, and for nursing time to be released for other duties or roles in the pre-op clinic. To further maximise the skill mix and resource in the multi-professional team and to enhance patient safety and experience, registered pharmacy technicians who complete specific PGD training and are deemed competent, could supply patients with pre-operative bowel cleansing preparations (prior to colorectal surgery) or prescription only medication for pre-op Methicillin-resistant Staphylococcus aureus (MRSA) decolonisation.

The pharmacy technician's underpinning knowledge, skills and competency support their role in:

- assessing patient suitability and eligibility (including interpretation of patient results and medication history)
- assessing consent
- providing verbal and written advice and information to ensure appropriate administration by the patient
- documentation in patient's record
- referral to clinicians, where appropriate

Governance and patient safety

As with any of the professions authorised to use PGDs, registered pharmacy technicians will be required to demonstrate they are competent to do so.

The governance involved in developing a PGD ensures there is clear accountability, delegation, monitoring and a structured work programme for reviewing, updating and re-authorising PGDs. Together with the governance set by the professional regulator (see below), these measures provide assurance to patients and healthcare professional colleagues that registered pharmacy technicians can supply and administer medicines using a PGD safely and appropriately.

The role of a pharmacy technician

Pharmacy technicians are involved in the procurement, storage, supply, preparation, administration and education of medicines and medicinal products. They work as part of multi-professional teams and provide medicines optimisation services. Place-based training of pharmacy technicians provides exposure to the clinical setting in which they will be delivering medicines optimisation services. These clinical settings include:

- acute hospital pharmacy, wards, dispensaries, technical service (aseptic) units
- community pharmacy
- primary care - GP surgeries, care homes
- health and justice settings
- mental health settings
- community services

Initial training

Pre-registration trainee pharmacy technicians undertake a 2-year training programme and must achieve GPhC-approved education that meets the 2017 initial education and training standards. The underpinning curricula as a minimum includes:

- chemistry
- microbiology
- physiology
- action and uses of medicines
- law

- pharmaceutics
- dispensing
- pharmacy production
- professional practice
- ethical decision-making
- medicines optimisation
- accuracy-checking

Pharmacy technician training involves the completion of combined knowledge and competence-based qualifications or courses. The GPhC accredits and recognises these courses and qualifications, which lead to registration. They may be delivered face to face or at a distance. Awarding bodies - Edexcel (Pearson), NCFE Council for Awards in Care, Health and Education, Open Awards, and the Scottish Qualifications Authority - approve courses delivered in further education colleges and NHS trusts or health boards as well as providing external verification and quality assurance of assessments. These courses and their quality assurance arrangements are ‘recognised’ by the GPhC, in contrast to programme providers (for example, delivered by Buttercups Training and the University of East Anglia) which are accredited directly by the GPhC. There are also approved apprenticeship pathways made up of qualifications and courses which are integrated in terms of the end point assessment requirement of the pharmacy technician apprenticeship standard.

Pre-registration trainee pharmacy technicians must provide evidence of having completed a minimum of 2 years relevant work-based experience in the UK as part of the GPhC registration criteria. This must have been under the supervision, direction or guidance of a pharmacist or pharmacy technician to whom they have been directly accountable for no less than 14 hours per week. During these 2 training years, they must have completed at least 1,260 hours of work experience (excluding sickness absence, maternity leave and holidays) and at least 315 hours of work experience in each year.

Professional regulation of pharmacy technicians

The term ‘pharmacy technician’ is a protected title by law. All pharmacy technicians, whether working in the NHS, private or voluntary sectors in England, Wales and Scotland, must be registered with the General Pharmaceutical Council, the statutory regulator for pharmacy professionals in Great Britain. In February 2023, there were 25,191 pharmacy technicians registered with the GPhC, the vast majority of whom were employed in the community pharmacy sector.

The purpose of professional regulation is to protect the public and give them assurance that they will receive safe and effective care when using pharmacy

services. The GPhC sets the professional standards that all registered pharmacy technicians must meet in relation to their education, training, conduct, performance, ethics and health. These are the minimum standards the GPhC considers necessary to protect members of the public. Registrants must meet all these standards when they first register and complete a professional declaration. Thereafter they must annually meet revalidation requirements to demonstrate continued fitness to practise.

PGDs can only be used by registered healthcare professionals who remain accountable to their professional regulator. Professional regulators have powers to take action against registrants whose practice does not comply with professional standards. An individual using a PGD must also be specifically authorised to supply and administer against that specific PGD. They are professionally accountable for each patient who is treated using a PGD and are responsible for the patient's safety in the process. The standards set by the GPhC add an additional layer of governance to the existing protections a PGD provides, ensuring patient safety in the supply and administration of medicines.

Pharmacy technicians are not currently a registered healthcare profession in Northern Ireland. However, a public consultation on the proposal for pharmacy technicians to become regulated closed on 16 May 2022 and this policy is being progressed.

Continuing professional development and revalidation

Registered pharmacy technicians (and pharmacists) must demonstrate annually that they continue to practise both safely and effectively within their scope of practice to maintain their registration. This is known as revalidation. It is designed to demonstrate how pharmacy technicians have kept their professional skills and knowledge up to date, how they have reflected on their practice to help them improve, and how they have provided safe and effective care to patients and the public, as set out in the standards for pharmacy professionals.

To demonstrate this, pharmacy technicians must submit evidence of both planned and unplanned continuing professional development, a peer review and a reflective account. These records are reviewed on a partly targeted and partly random basis with feedback provided. A failure to meet the standards set by the regulator, or to submit their revalidation records when renewing their annual registration, may lead to the GPhC placing restrictions on a pharmacy technician's practice and may lead to removal from the register. The GPhC will be considering any further development of the revalidation framework as part of its wider look at post-registration assurance of practice.

Association of Pharmacy Technicians UK

The Association of Pharmacy Technicians UK (APTUK) was established in 1952 and became the professional leadership body representing pharmacy technicians working in all sectors across the UK in 2011. APTUK provides advice, information and support to their members, advocates for and represents the profession, and enhances the education and scope of practice of pharmacy technicians.

Professional accountability of pharmacy technicians

Pharmacy technicians must ensure they provide evidence-based care within their scope of practice and competence. Should legislation be amended, when using PGDs to supply or administer medicines, they will be professionally accountable for their decisions, including actions and omissions. This also means that, even though pharmacy technicians could supply or administer a medicine legally, they are not obliged to do so and must work within GPhC standards at all times. Pharmacy technicians must have due regard to patient safety information and should be aware of, change and update their practice accordingly, which may include not using a PGD until it is amended or reviewed in light of the guidance.

Pharmacy technicians are accountable for their own practice as registrants but currently work under the direct supervision of pharmacists for the sale, supply and preparation of medicines. Supervision legislation in the Medicines Act is currently being reviewed to reflect how the profession can be enabled to provide further patient-focused clinical services to support better patient health outcomes, reflecting the registered status of pharmacy technicians in Great Britain. The Department of Health and Social Care (DHSC) aims to consult on legislative proposals on supervision in autumn 2023.

Safe use of PGDs

The National Institute of Clinical Excellence (NICE) has developed a Medicines practice guideline (https://www.nice.org.uk/guidance/mpg2) on the writing, authorisation, implementation and use of PGDs. They also provide a suite of tools for organisations, services and individuals to structure training and governance, and a set of standards against which organisations can monitor their performance. This guidance applies to England and Wales and is available for use in Scotland and Northern Ireland.

The NHS Specialist Pharmacy Service (SPS) is commissioned by NHS England to provide expert pharmaceutical support and guidance relating to all aspects of the use of PGDs through online information and national PGD templates. The information offered is publicly available and in line with NICE

guidance. It is applicable to England but can also be accessed by the devolved governments.

Eligibility and training to use PGDs

NICE guidance states that appropriate training, regular re-training and assessment of competency is important for all people involved with PGDs to reduce variation and deliver safe and effective services in which PGDs are used. Competency must be assessed, and an appropriate training programme should be developed for all of those involved in considering the need for developing, authorising, using and updating PGDs.

NICE has developed and published competency frameworks for people developing, updating, authorising and using PGDs to support this guideline. Locally written training programmes may be provided by organisations for their own staff. The e-learning package written by the SPS in partnership with UK Health Security Agency (UKHSA) and Health Education England (HEE) is freely available to support healthcare professionals who use, develop, authorise, review or update PGDs to deliver services in line with legislation and NICE guidance.

Registration as a pharmacy technician does not automatically warrant use of all PGDs. Registered pharmacy technicians are required to undertake additional training as defined in each PGD to ensure only those who have been assessed as fully competent and qualified and who have completed the relevant PGD specific training may work under a PGD. This is aligned with the practice for all other healthcare professionals that can supply and administer medicines under a PGD.

Local governance of PGDs

PGDs are locally governed. Organisations already have governance arrangements in place for other professions that use PGDs, and pharmacy technicians would be expected to comply with these where the PGD is appropriate for their use. Arrangements include:

- involvement in writing and authorisation (if a new PGD is being developed or upon routine review)
- implementation of PGDs at service level
- expectation and provision of training
- assurance of competence to supply or administer the medicines included in the PGD by the service lead
- oversight of PGDs in the organisation in which staff are using them
- audits of use and impact

When developing their own PGDs, providers are required to ensure they are aware of and follow the regulatory requirements for all areas of development, authorisation and use. The NICE guideline for PGDs recommends that

organisations should agree and undertake a planned programme of monitoring and evaluation of PGD use within the service. They must keep a record of all the healthcare professionals authorised to practise under the PGD. Authorised healthcare professionals must record an agreement to follow the PGD. They must provide assurances that they are trained and competent to do so.

All PGDs have clearly defined governance and education frameworks. This is quality assured by the NHS as an employer or commissioner. Healthcare professionals who will be using the PGD must be named and authorised before they use it to provide care. An appropriate member of staff - for example a GP, practice manager or lead nurse - must be responsible for authorising the healthcare professionals in each organisation. Practitioners should keep a copy of their individual authorisation and have the current authorised PGD available for reference.

Online practice and PGDs

The legal framework for PGDs does not state that an individual must be present for a supply of medicine to be made. Therefore, remote consultation prior to making a supply under a PGD is permissible and a supply can also be made in the absence of the individual themselves. The SPS has provided advice on ensuring safe care and good governance when supplying medicines remotely under a PGD (https://www.sps.nhs.uk/articles/patient-group-direction-use-in-remote-consultations/).

The advice states that healthcare professionals must ensure an adequate assessment can still be conducted in a remote consultation in line with requirements for PGDs, and to the same standard as a face to face consultation. No part of the clinical assessment process, or the decision on suitability for a medicine to be supplied, can be delegated to, or undertaken by another person. Organisations must also consider how informed consent during remote consultations is obtained and documented and ensure the principles of shared decision-making are upheld.

Developing and authorising PGDs

Organisations should not develop a new PGD until they have ensured there is not one for that medicine already in use within their organisation, or in another, which they can use as a template and adapt as required. The SPS has developed PGD templates for a range of medicines, which must be clinically signed and authorised and adapted by local organisations (NHS or providing NHS commissioned services). These have been developed with experts for

clinical specialties and are intended to reduce duplication and variation and improve the consistency of care.

In addition, UKHSA produces PGD templates to support national immunisation programmes provided on the NHS. In the absence of an available PGD template, NICE and the SPS have developed standard blank templates and best practice guidance on the development and authorisation of PGDs. The SPS has developed an e-learning programme in partnership with UKHSA, HEE and e-Learning for Healthcare, which is designed to support healthcare professionals who use, develop, review or update PGDs to deliver services in line with legislation and NICE guidance.

Implementation of new legislation under enabling powers

We do not expect large numbers of new PGDs to be developed specifically for use by registered pharmacy technicians. The legislative change is enabling and is more likely to be used to give registered pharmacy technicians (who complete specific PGD training and are deemed competent) the ability to use PGDs which are already utilised within an organisation, enabling them to be further utilised as part of the workforce, adding more value to multi-professional teams.

Adverse drug reactions, interactions and errors

Registered pharmacy technicians working under a PGD are expected to be able to recognise common side effects and adverse reactions to the medicines they administer and to know when there is a potential risk of an interaction. This knowledge is supported within pharmacy technicians' initial education and training, which requires them to be able to recognise adverse drug reactions and interactions and respond appropriately. If a patient experiences an adverse reaction to a medication, once the required treatment has been undertaken, this should be recorded in the patient's notes. The pharmacy technician should notify the Medicines and Healthcare products Regulatory Agency via the Yellow Card scheme, where appropriate.

If an error in supply or administration occurs while using PGDs, pharmacy technicians must take immediate action to manage the effects on the patient and mitigate potential side effects to the patient, and must report the error as soon as possible according to local protocols. The reporting of errors must be in an open and transparent way so that anything learned from the incident is shared as appropriate.

Human Medicines Regulations 2012

The HMRs set out a comprehensive regime for the authorisation of medicinal products, including the sale, supply and administration of medicines. The powers which allow registered healthcare professionals to sell, supply and/or administer medicines to patients using PGDs are contained in part 12 when read with schedule 16 of the HMRs.

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 that affect Northern Ireland and made under the MMD Act 2021, are made by the UK and Northern Ireland ministers. This consultation is being conducted in the names of the Secretary of State for Health and Social Care (in so far as they relate to England and Wales and Scotland) and with the Department of Health in Northern Ireland (in so far as they relate to Northern Ireland). At present, Northern Ireland pharmacy technicians are not registered and will not come within the scope of pharmacy technicians who can use PGDs until the time they are registered. However, once pharmacy technicians in Northern Ireland become a registered healthcare profession, a further amendment to the HMRs may be made so they can use PGDs also.

Legal duties

The general equality duty that is set out in the Equality Act 2010 (https://www.legislation.gov.uk/ukpga/2010/15/contents) requires public authorities, in the exercise of their functions, to have due regard to the need to:

- eliminate unlawful discrimination, harassment and victimisation and other conduct prohibited by the act
- advance equality of opportunity between people who share a protected characteristic and those who do not
- foster good relations between people who share a protected characteristic and those who do not

We do not consider this proposal to have any differential negative impacts on individuals with protected characteristics. If a patient can be assessed and any supply and/or administration can be made safely under a PGD without redirecting them to another prescriber, then this policy has the ability to remove barriers to patients in receiving the care and support they need, including the elimination of unlawful discrimination and fostering good relationships by increasing access to clinical services in the community.

This proposal has the potential to help community pharmacy deliver more patient-facing clinical services, further integrating them into the NHS and allowing them to become the first contact for minor self-limiting illnesses. This may advance equality of opportunity as it could provide more local and convenient access to medicines and a greater choice of professionals with which patients can discuss their treatment.

The National Health Service Act 2006 (https://www.legislation.gov.uk/ukpga/2006/41/contents) contains a number of overarching duties on the Secretary of State for Health which apply to every action undertaken in relation to the NHS and public health. These duties include:

- the duty to continue to promote a comprehensive health service in England (section 1)

We believe this proposal supports the duty to promote a comprehensive health service in England as it supports utilisation of the skills of the whole pharmacy team, allowing them to maximise their contribution in the provision of clinical services. The use of PGDs by registered pharmacy technicians means that certain clinical services can be offered without requiring a pharmacist or other prescribing professional to supply and administer medicines themselves or to assess the patient and write a PSD. This will free up pharmacists' time which could be used to focus their clinical expertise on treating more complex cases as independent prescribers. This is pertinent as initial education and training reforms for pharmacists will see pharmacists become independent prescribers from the point of registration from 2026 onwards.

- the duty as to improvement in quality of services (section 1A)

We believe this also contributes to improvement in the quality of services via facilitating timely access to medicines. The ability for additional healthcare professionals to supply and/or administer medicines where it is safe and appropriate to do so will provide patients with more options for receiving the right treatment, at the right time, reducing delay. This will contribute to better patient outcomes by better using the skill mix within healthcare professions to provide additional capacity to treat patients providing new routes for access to pharmaceutical services.

Under current legislation, the only mechanism by which registered pharmacy technicians can supply and administer medicines is where they are authorised to do so by a PSD. As registered healthcare professionals, this does not fully utilise the skills and knowledge of registered pharmacy technicians who could use their education and training to supply and administer medicines safely under a PGD. If PGDs were in place, registered pharmacy technicians could administer specific medicines under an appropriate PGD without requiring the intervention of trained prescribers. This will enable registered pharmacy technicians to take responsibility for their decision to administer and supply medicines in accordance with the written PGD.

- the duty as to reducing inequalities (section 1C)

PGDs provide a structured framework which permits certain healthcare professionals to supply and/or administer medicines to a pre-defined group of patients. Increasing the accessibility of medicines for those within the defined patient group could help free capacity for appointments within other parts of the healthcare system. Any patient that falls outside the pre-defined group cannot be treated under that PGD and must be referred to an independent prescriber for an individual assessment.

Consultation questions

Question

Do you agree or disagree with the proposal to amend the Human Medicines Regulations (2012) to enable pharmacy technicians to supply and administer medicines to patients using PGDs?

- agree
- disagree
- don’t know

If you have any additional information to support your answer, please provide details (maximum 150 words).

Question

Do you agree or disagree that the 2-year pre-registration training equips pharmacy technicians with the appropriate knowledge and skills to complete the training requirements which allow them to use PGDs?

- agree
- disagree
- don’t know

If you have any additional information to support your answer, please provide details (maximum 150 words).

Question

Do you agree or disagree that allowing pharmacy technicians to supply and/or administer under a PGD will enable safe access to medicines for

patients?

- agree
- disagree
- don’t know

If you have any additional information to support your answer, please provide details (maximum 150 words).

Question

This proposal is to allow registered pharmacy technicians to supply and administer medicines using a PGD.

Do you have additional information in support of this proposal? (maximum 150 words)

Do you have additional information for why this proposal should not go ahead? (maximum 150 words)

Question

Do you agree or disagree that the consultation stage impact assessment gives a realistic indication of the likely costs, benefits and risks of the proposal?

- agree
- disagree
- don’t know

If you have any additional information to support your answer, please provide details (maximum 150 words).

NI respondents: equality and rural screening

In Northern Ireland new policies must be screened under Section 75 of the Northern Ireland Act 1998 (https://www.legislation.gov.uk/ukpga/1998/47/contents), which places a statutory duty on public authorities to mainstream equality in all its functions so that equality of opportunity and good relations are central to policy-making and service delivery. In addition, new or revised policies must be rural-proofed in line with the Rural Needs Act (NI) 2016

(https://www.legislation.gov.uk/nia/2016/19/contents), which requires public authorities to have due regard to rural needs.

Question

We do not consider that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in NI.

If you agree or disagree, we welcome views on this point (maximum 150 words).

Question

Do you agree or disagree that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in NI?

- agree
- disagree
- don't know

If you agree or disagree and have evidence to support your answer, please provide details (maximum 150 words).

Question

Do you agree or disagree that the proposal risks impacting people differently with reference to their (or could impact adversely on any of the) protected characteristics covered by the public sector equality duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998?

- agree
- disagree
- don't know

Please explain your answer (maximum 150 words).

How to respond

The government invites responses on the specific questions raised. The questions can be found in the document.

Please respond through our online consultation survey (https://consultations.dhsc.gov.uk/64ca5615ec909ca1ad006687).

If you have any queries on this consultation or require an alternative format, please email hrtppcenquiries@dhsc.gov.uk. Do not send your consultation answers or any personal information to this email address.

> If you have tried to message the mailbox since Monday 11 September, please resend your message to hrtppcenquiries@dhsc.gov.uk.

If you do not have internet or email access, then please write to:

> Prescribing Policy and Charges Team
> Department of Health and Social Care
> Floor 2, Area G, Quarry House
> Quarry Hill
> Leeds
> LS2 7UE

The consultation is open for a period of 6 weeks. Please submit your responses to the questions by 11:59pm on 29 September 2023.

Annex A: legal basis and assessment of the matters set out in section 2 of the Medicines and Medical Devices Act 2021

The Medicines and Medical Devices Act 2021 (MMD Act) came into force on 11 April 2021. We propose to make legislative changes using powers in Part 2 of the MMD Act, which provides powers to make, among other things, amendments to the HMRs.

This consultation is conducted in line with the requirement to consult in section 45(1) of the MMD Act.

Section 2 of the MMD Act provides that patient safety must be the overarching objective of the appropriate authority when making regulations. Section 2 requires that when assessing whether regulations would contribute to the objective of safeguarding public health, the appropriate authority must have regard to 3 factors:

- the safety of human medicines and that the benefits of doing so outweigh any risks
- the availability of human medicines
- the likelihood of the relevant part of the United Kingdom being seen as a favourable place in which to:
  - carry out research relating to human medicines
  - conduct clinical trials
  - manufacture or supply human medicines

As set out in section 2(3) of the MMD Act, where regulations under section 2(1) may have an impact on the safety of human medicines, the appropriate authority may make the regulations only if the authority considers that the benefits of doing so outweigh the risks.

The appropriate authority is the Secretary of State for Health and Social Care in relation to Great Britain and, in relation to Northern Ireland, it is the NI Department of Health and the Secretary of State jointly. The consultation obligation applies to both the Secretary of State and Northern Ireland Department of Health, and both will make the final decision on making any legislative changes under section 2(1).

Below we have assessed the proposals against each of the factors set out in section 2.

Continued monitoring of patient safety

PGDs make one named healthcare professional responsible for assessing a patient and supplying or administering a medicine to them. PGDs are useful where assessment and treatment follows a clearly predictable pattern. Within a PGD the suitability of supply and/or administration is determined by a set of instructions which directs the healthcare professional in their assessment of the patient. This is known as ‘the direction’. Any patients who fall outside of the pre-defined patient group within the PGD will be referred to an independent prescriber for an individual assessment.

PGDs are developed by multi-professional groups with extensive expertise, requiring a significant amount of time and resource to develop and implement. Once implemented, PGDs are subject to ongoing monitoring. All users of PGDs, including registered pharmacy technicians, are required to undertake additional training, as defined in each PGD, to be able to supply and administer any medicines under the relevant PGD. In addition, NICE guidelines recommend that organisations should agree and undertake a planned programme of monitoring and evaluation of PGD use within the service.

For all the reasons explained above, the likelihood of any increased risk of inappropriate administration of medicines is considered to be very low and is outweighed by the benefits of this proposal.

Increased availability of medicines and services

The policy has the potential for individuals to receive the treatment they need faster than if they needed to wait for another healthcare professional to prescribe, supply or administer the medicine they require. Allowing registered pharmacy technicians to undertake more clinical services via a PGD will also increase capacity for pharmacists to focus their clinical expertise and prescribing skills. Ultimately, this gives patients access to a wider range of services delivered by healthcare professionals with the right level of skills at the right time, supporting better patient healthcare outcomes and reducing the need for appointments in other parts of the healthcare system.

UK favourability to supply medicines

This proposal has the potential to have a positive impact on the UK being seen as a favourable place to supply medicines. It demonstrates that the UK has the adaptability to evolve its service design to meet the medicines requirements of local populations and to develop the capabilities of its healthcare professionals. The utilisation of the skills of pharmacy technicians will help to expand the range of patient-facing clinical services which can be offered within community pharmacies and enable registered pharmacy technicians to contribute more as part of multi-professional teams in other settings. This will improve safe and timely access to medicines, reducing delays in care. This demonstrates a forward-thinking approach to the provision of medicines which we believe will influence the likelihood of the UK being seen as a favourable place in which to supply human medicines.

Annex B: privacy notice

The Department of Health and Social Care (DHSC) is the data controller.

What personal data we collect

We will collect the following type of personal information:

- age
- sex
- gender
- area of UK respondents are based in
- ethnic group
- field of work
- job title
- organisation details
- email address

How we use your data (purposes)

The data we collect is to inform DHSC of the demographic of respondents. The department will process your personal data in accordance with the Data Protection Act 1998 (https://www.legislation.gov.uk/ukpga/1998/29/contents) (DPA) and in most circumstances this will mean that your personal data will not be disclosed to third parties. We may need to contact you if we have had a request under the Freedom of Information Act 2000 (https://www.legislation.gov.uk/ukpga/2000/36/contents) (FOIA). We will also email you to let you know if we have published a response to the consultation.

Legal basis for processing personal data

Under the General Data Protection Regulation (GDPR), the lawful basis we rely on for processing this information is:

- Article 6(1)(e) UK GDPR
- Article (9)(i) UK GDPR

Data processors and other recipients of personal data

The Department of Health and Social Care is the data processor. Response data from respondents who have informed us that they are in Northern Ireland will be shared with officials from the Department of Health in Northern Ireland. The Northern Ireland dataset will be anonymised, names and email addresses

will be removed and replaced with a response ID. If follow up of any of the responses is required by the Department of Health in Northern Ireland, this will be undertaken by DHSC.

International data transfers and storage locations

Any personal information collected will be stored in the UK and managed in line with DHSC's personal information charter.

Retention and disposal policy

We manage the information you provide in response to this consultation in accordance with DHSC's data protection policy. We will retain your data for 12 months after the consultation closes.

How we keep your data secure

Anyone managing and handling personal information understands that they are contractually responsible for following good data protection practice, are appropriately trained to do so, and are appropriately supervised.

Your rights as a data subject

By law, data subjects have a number of rights and this processing does not take away or reduce these rights under the EU General Data Protection Regulation (2016/679) and the UK Data Protection Act 2018.

These rights are:

- the right to get copies of information - individuals have the right to ask for a copy of any information about them that is used
- the right to get information corrected - individuals have the right to ask for any information held about them that they think is inaccurate, to be corrected
- the right to limit how the information is used - individuals have the right to ask for any of the information held about them to be restricted, for example, if they think inaccurate information is being used

- the right to object to the information being used - individuals can ask for any information held about them to not be used. However, this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case
- the right to get information deleted - this is not an absolute right, and continued use of the information may be necessary, with individuals being advised if this is the case

Comments or complaints

Anyone unhappy or wishing to complain about how personal data is used as part of this programme, should contact data_protection@dhsc.gov.uk in the first instance or write to:

> Data Protection Officer
> 1st Floor North
> 39 Victoria Street
> London
> SW1H 0EU

Anyone who is still not satisfied can complain to the Information Commissioners Office. Their website address is www.ico.org.uk (http://www.ico.org.uk/) and their postal address is:

> Information Commissioner's Office
> Wycliffe House
> Water Lane
> Wilmslow
> Cheshire
> SK9 5AF

Automated decision-making or profiling

No decision will be made about individuals solely based on automated decision-making (where a decision is taken about them using an electronic system without human involvement) which has a significant impact on them.

Changes to this policy

This privacy notice is kept under regular review, and new versions will be available on our privacy notice page on our website. This privacy notice was last updated on 18 August 2023.

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