Department of Health & Social Care

Pharmacy supervision consultation response

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Foreword

Message from the 4 chief pharmaceutical officers of the UK

Pharmacists and pharmacy technicians play a critical role in ensuring people have safe, timely access to medicines and that patients and health and social care professionals receive the information, advice and support they need to optimise the way medicines are prescribed, presented and taken. Enabling every pharmacist and pharmacy technician to fully use their unique training and expertise helps to deliver significant benefits for patients and the wider NHS.

Pharmacy supervision consultation

The pharmacy supervision consultation, launched in December 2023, set out proposals to put in place a legal framework for delegation within a pharmacy or pharmacy service and release time for pharmacists to provide pharmaceutical and clinical care for patients. The proposals recognise the significant advances that have been made in pharmacy technicians' practice since the profession first began to be regulated in Great Britain in 2011, and the potential to use the profession's skills more effectively in the delivery of pharmacy services across all parts of the NHS.

These are important issues, and we are delighted with the level of engagement the consultation received. More than 5,000 individuals and organisations shared their views and have helped shape the proposals for reform of supervision within pharmacies and pharmacy services across the UK.

We are encouraged that the vast majority of organisations who responded to this consultation welcomed the proposals and are grateful for the rigour and constructive feedback provided by every respondent. We have considered all responses and used them to help strengthen the proposals in drafting the legislation. It was also used in our consideration of the work that will be required by regulators and professional bodies to ensure the reforms reinforce the continuing role pharmacies and pharmacy services have in the safe and effective supply of medicines to the public.

Response from the profession

While professional leadership bodies, trade bodies and individual pharmacy technicians mostly agreed with the proposals, we recognise that many individual pharmacists responding to the consultation did not. We have taken time to reflect on the important issues raised by those pharmacists who are concerned by the changes and understand we need to do more to communicate how these changes will benefit and enable the pharmacist profession in the future. Enabling pharmacists to more fully use their training, skills and expertise will benefit patients and also make careers more professionally

rewarding. In that sense, the professional development of pharmacists and pharmacy technicians goes hand in hand. But we also recognise the need to do more to promote our plans for how pharmacy services and the pharmacy workforce will develop in the future to assure and mitigate the concerns expressed by some respondents.

We understand that many professionals expressed cautious or conditional agreement with the changes and that some wished to hold back their agreement until they could see the detail of how reforms will be implemented in practice. This response begins to set out the type of supporting measures that will be put in place alongside the legislative changes. As the legislative reforms progress, we will continue to work closely with the pharmacy regulators in Great Britain and Northern Ireland to shape the detail of how the reforms will play out in practice. It is imperative that pharmacists and pharmacy technicians and their representative bodies continue to engage with this process and the work of the General Pharmaceutical Council (GPhC) and Pharmaceutical Society of Northern Ireland (PSNI) to ensure the legislative changes deliver the policy intention while continuing to protect patients and the public.

In our foreword to the consultation, we stressed our commitment to the principle of a pharmacist being responsible for and present in every community pharmacy. The continued access to the clinical advice and expertise of pharmacists in every community, in every part of the UK, is critical to delivering the ambition shared by all 4 UK governments - to provide clinical services that more fully use pharmacists' training, knowledge and skills. Nothing in these proposals removes the requirement for the presence of a responsible pharmacist in every retail pharmacy, which is enshrined in primary legislation.

We are pleased that the majority of pharmacy technicians welcomed the changes. It is clear pharmacy technicians are ready to take the opportunity to work more autonomously within an agreed regulatory framework and embrace the responsibilities which come with being a registered and regulated health professional.

Of the 3 proposals put forward in the consultation, it is the third, to allow pharmacy technicians to supervise hospital aseptic facilities without being authorised to do so by a pharmacist, that has split views, most of which were among stakeholders working in aseptic services. We are grateful for the time colleagues from committees and groups spanning quality assurance, pharmaceutical production, aseptic services, advanced therapy medicinal products, education and training and others have taken to set out their concerns, and for engaging with us constructively on points of detail since the consultation closed. Our understanding is that these groups support the overall objectives of the proposed legislative changes, and we will progress further work to ensure the legislative changes are supported by appropriate regulatory standards, education and training and professional guidance to secure their safe implementation.

Finally, we can reassure all respondents that the proposed legislative changes are enabling, but do not mandate changes to practice. They are designed to allow pharmacists to be more accessible to patients and do not change individuals' professional responsibility to work within their competence regardless of permissions given in legislation.

Next steps

The next phase of this work will define the regulatory and professional standards that support the implementation of the reforms in practice. This phase will be of great interest to the many individuals who responded to this consultation wanting more detail on how these proposals will be implemented. Organisations and individuals will have the opportunity to share their views and influence how these proposals are taken forward safely as work progresses with regulators and professional leadership bodies.

Thank you to respondents - your views have shaped the reforms and will enable pharmacists and pharmacy technicians to further develop their professional practice. This will enable them to make the most of new opportunities and working confidently as part of multi-professional NHS teams, while continuing to play a critical role in the delivery of healthcare to patients and local communities.

Executive summary

The Department of Health and Social Care (DHSC), on behalf of the 4 UK health departments, held a public consultation from 7 December 2023 to 29 February 2024 on proposals to make amendments to the Human Medicines Regulations 2012 (HMR) and the Medicines Act 1968 (the Medicines Act). This would ensure the legislation governing the requirements for a pharmacist to supervise specified activities in a pharmacy or pharmacy service meets the changing nature of pharmacy practice in all parts of the UK.

There is a clear ambition across the UK to maximise the contribution pharmacists and pharmacy technicians make to address the challenges faced by the NHS. The legal requirement for supervision of activities (the preparation, assembly, dispensing, sale and supply of medicines) taking place in pharmacies in the community, hospitals and other relevant settings defines how pharmacy services are currently provided. While significant progress has already been made to expand the roles of pharmacists and pharmacy technicians, the current supervision requirements can act as an impediment to the most effective use of all members of the pharmacy workforce.

The consultation sought responses to 3 proposals which would amend the HMR and the Medicines Act to:

- enable pharmacists to authorise pharmacy technicians to carry out, or supervise others carrying out, the preparation, assembly, dispensing, and sale and supply of medicines

- enable pharmacists to authorise any member of the pharmacy team to hand out checked and bagged prescriptions in the absence of a pharmacist

- allow pharmacy technicians to take primary responsibility for the preparation, assembly and dispensing of medicinal products in hospital aseptic facilities that do not have a specials manufacturer's licence

The proposals put in place a legal framework for delegation within a pharmacy or pharmacy service. The changes are enabling, not prescriptive, and are designed to enable pharmacists to spend less time on tasks that can be safely delegated and more time delivering clinical services, further benefitting the public. This is:

- not about removing pharmacists from pharmacies

- not about allowing remote supervision

- not about removing the need for pharmacists to undertake appropriate clinical checks linked to the dispensing process - for example, carrying out the clinical check on a prescription

On the contrary, it is about enabling pharmacists to better use their unique clinical skills and releasing more time for them to provide expert advice and care to maximise the benefit patients get from their medicines. It also recognises the training and expertise of pharmacy technicians and enables them to take responsibility for many activities in the pharmacy which previously would have been solely the responsibility of a pharmacist. These proposals will therefore result in the more effective use of the knowledge and skills of every member of the pharmacy team, optimising how they work together in all settings to increase capacity in the wider NHS.

To confirm, pharmacy technicians are not currently subject to statutory regulation in Northern Ireland and therefore all references to pharmacy technician regulation in this document refer to pharmacy technicians in England, Scotland and Wales. When pharmacy technicians become a registered profession in Northern Ireland, we will work with the Northern Ireland Department of Health to enact the changes as soon as possible.

Introduction

This consultation sought views on proposals to modernise medicines legislation governing which tasks must be undertaken by a pharmacist, or under the supervision of a pharmacist, in a community pharmacy, hospital or other relevant setting. This work is part of a series of reforms to provide greater flexibility in how pharmacy services work and deploy staff, and enable better use of the skills of the whole pharmacy team.

This consultation delivered on the ambitions described by each of the 4 health departments on the future of pharmacy in England, Scotland, Wales and Northern Ireland. This work complements earlier work to:

- enable registered pharmacy technicians to use patient group directions
- give pharmacies the flexibility to dispense medicines in their original packs
- enable all community pharmacists to benefit from ‘hub and spoke’ dispensing models

There is a clear ambition across the UK to maximise the contribution pharmacists, pharmacy technicians and the wider pharmacy team can make to address the challenges faced by the NHS. Across the UK, around 1.3 billion prescription items are dispensed in the community each year. Making efficiencies to dispensing processes and recognising and more effectively using the skills of every member of the pharmacy team will enable pharmacies to deliver both critical dispensing services and an increasing number and range of patient-facing clinical services. These reforms aim to improve career progression and job satisfaction for the whole team and improve patient and public experience when accessing pharmacy services, whether on the high street, in hospital, clinics or care homes.

Government legislation will set the broad framework and will not set out detailed practice matters (for example, the necessary steps to demonstrate competence to perform specific tasks or record keeping concerning an authorisation). This allows for the pharmacy regulators to consult on and set out the detail in their rules, regulations and/or standards. Professional bodies can then support the safe and effective development of practice through associated guidance.

GPhC is already progressing its strengthening pharmacy governance work, which aims to provide clarity around how pharmacies are organised and managed to help make sure patients and the public continue to receive safe and effective pharmaceutical care. In January 2025, GPhC published new Standards for Chief Pharmacists which set out the professional responsibilities of these pharmacists who are senior healthcare professionals responsible for providing leadership, expertise, and oversight and management of pharmacy services within their organisations. This will be followed by the development and

consultation on rules and standards for responsible pharmacists and superintendent pharmacists, and revision of the standards for initial education and training of pharmacy technicians.

The draft legislation we are proposing will be subject to a transition period to allow time for this underpinning work to be completed before any changes are safely implemented in practice.

Most of the new arrangements will initially apply in Great Britain only, as pharmacy technicians are not currently a regulated profession in Northern Ireland. Our aim is to apply this legislation in Northern Ireland as soon as possible.

As a result of the public consultation and consideration of the responses, the government has laid the draft Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2025 before Parliament under the powers in section 60 of the Health Act 1999.

This document sets out what we heard in response to the consultation and, as a result, what measures the UK government - with the support of devolved governments - intends to bring forward to the Westminster Parliament.

Summary of proposals

The legislative proposals are enabling. This means pharmacies will be able to continue to operate as they do now after the changes come into force and to introduce changes in their practice later or not at all (recognising this will mean those pharmacies may forgo the benefits of the changes).

Proposal 1: introducing authorisation of a pharmacy technician by a pharmacist

Currently, section 10(1) of the Medicines Act and regulations 4 and 220 of HMR enable the preparation, assembly, dispensing, and sale and supply of medicines by a pharmacist, or under the supervision of a pharmacist, in specified settings. These proposals will enable these activities to be done by, or under the supervision of, a pharmacy technician when the pharmacy technician has been authorised to do so by a pharmacist. A pharmacy technician who has been authorised does not need to be directly supervised by a pharmacist, freeing up pharmacists' time to deliver other clinical services. This does not mean a pharmacist is completely removed from the dispensing process. Pharmacists will still need to be involved in certain processes, including checking the clinical appropriateness of a prescription. Nothing in these proposals changes the requirement for a responsible pharmacist and superintendent pharmacist to be in charge of, and responsible for, the safe and effective operation of a retail pharmacy business.

These new arrangements will initially only apply in Great Britain as pharmacy technicians are not currently a regulated profession in Northern Ireland. Our aim is to apply this legislation in Northern Ireland once this is possible.

Proposal 2: the handing out of pre-checked and bagged medicines to patients in the absence of a pharmacist

Under these proposals, a new Regulation 220B will be inserted into the HMR, enabling pharmacists to authorise any member of the pharmacy team to hand out dispensed prescriptions, which have been checked for clinical appropriateness and accuracy, in the absence of the pharmacist (for example, when the pharmacist is not interruptible in a consultation room or temporarily absent from the premises). 'Absence' of the pharmacist is permitted and defined under section 72A of the Medicines Act and the subordinate Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008.

The law currently permits pharmacy staff to give a delivery driver medicines to take to the patient, or to place a medicine in an automated collection locker for collection by the patient or their representative. In these scenarios, medicines are handed over to patients without a pharmacist supervising the transaction. In contrast, when a medicine is handed to a patient or their representative in a registered pharmacy, a pharmacist needs to be in a position to hand over the medicines themselves or to supervise a member of staff doing so. This anomaly leads to patients experiencing delays in receiving medicines when the pharmacy is open but a pharmacist is temporarily absent (or treated as absent) from the pharmacy - for example, during a lunch or rest break. Our proposal will bring arrangements in community pharmacies in line with arrangements for automated lockers, collection points and home deliveries, and improve patient experience.

This proposal will apply to Great Britain and Northern Ireland.

Proposal 3: supervision by pharmacy technicians at hospital aseptic facilities

Under these proposals, a new regulation 4A will be inserted in the HMR which would permit pharmacy technicians in England, Scotland and Wales to supervise the preparation, assembly and dispensing of medicines in hospital aseptic facilities. This would enable suitably qualified and experienced pharmacy technicians to be responsible for a hospital aseptic facility without having to act under the supervision (or authorisation) of a pharmacist.

The demand for aseptically prepared medications is increasing with advances in medical science and the emergence of new, innovative medicines. Expanding the responsibilities of pharmacy technicians in hospital aseptic facilities will maximise the productivity of these aseptic facilities, bringing health benefits to patients.

To benefit from this provision, the pharmacy service must be overseen by a chief pharmacist (or someone fulfilling the statutory functions of a chief pharmacist) who is responsible for ensuring the safe and effective running of the pharmacy service.

As pharmacy technicians are not currently a regulated profession in Northern Ireland, this provision will initially only apply in Great Britain. Our aim is to apply this legislation in Northern Ireland once this is possible.

Summary and evaluation of responses

Pre-consultation engagement had been conducted with the sector and profession to inform these proposals, including with the Pharmacy Supervision Practice Group, representing community pharmacy and professional bodies. This work informed the consultation, which was conducted using an online consultation survey published on GOV.UK, which included tick-box style questions (asking respondents to agree, neither agree nor disagree, or disagree) as well as open-ended questions where respondents could write detailed comments to support their answers. There were 7 free text boxes, each of which had a limit of 350 words. Organisations or individuals sharing professional views could also submit written evidence to a dedicated mailbox.

Respondents could choose whether to answer each question, and the open-ended questions were not mandatory.

Approach to analysis

DHSC has analysed the responses and considered the feedback received. In doing so, we looked at the responses given to each of the questions posed as well as the information respondents provided in the free text sections of the consultation response survey, where people could share their views in their own words. We analysed responses to the open-ended questions using a theme modelling and tagging system. Theme modelling grouped similar responses for each question according to the words that best characterised their similarity. DHSC officials then reviewed these groups of words for each of the questions, alongside a sample of representative quotes, to determine an appropriate theme for each group of words. Multiple themes were tagged to capture nuanced and multifaceted responses.

Responses from organisations and individuals that did not use the online survey were manually processed to theme the responses. We determined the strength of the themes identified in the responses by counting the number of times a theme came up in the responses to a question.

Overview of the respondents

A total of 5,054 responses were received. Of these, 5,042 were received through the GOV.UK page and 13 were received by email.

A total of 96% (4,862) of responses were from individuals - sharing their professional or personal views - and 4% (192) were on behalf of organisations.

A total of 56% (2,890) of respondents stated that they were responding as a pharmacist, trainee or student pharmacist and 14% (701) of respondents stated that they were responding as a pharmacy technician or trainee pharmacy technician.

The consultation was UK-wide, with 84% (4,264) of respondents saying they lived in England, 7% (376) in Scotland, 3% (149) in Wales, 0.8% (38) in Northern Ireland and 0.2% (9) lived outside of the UK. A further 5% (218) respondents did not declare their location.

A breakdown of responses for each of the proposals is provided in annex 1.

Summary of consultation outcomes

The vast majority of responses from organisations - covering community pharmacy, NHS trusts, health boards, NHS integrated care boards, GPhC and professional leadership bodies, including the Royal Pharmaceutical Society (RPS) and Association of Pharmacy Technicians UK (APTUK) - supported the government proposals in the main. However, many responses from individual pharmacists disagreed with some or all of the proposals, mainly due to concerns about how the changes would be implemented in practice or with matters not related to the proposed legislation.

Respondents in favour of the proposals stated this would free up pharmacist time to better support patients and enable them to make better use of their clinical skills, and the skills of the wider pharmacy team.

There was recognition that the education and training of pharmacy technicians has developed over time, meaning the standards of initial education and training of some pharmacy technicians will depend on when they qualified. While this is true, all pharmacy technicians in Great Britain are required to be registered and regulated by GPhC and have a professional responsibility to work within their competence, referring anything outside their competence to others as appropriate. In addition, the chief pharmacist or superintendent pharmacist of the hospital or retail pharmacy business employing pharmacy technicians has their own professional obligations to ensure staff only undertake activities for which they are competent.

Additional post-registration training is widely available to support achieving competence, with assurance provided by the requirements for annual revalidation of all pharmacy technicians in Great Britain. This, combined with robust standard operating procedures and professional guidance, provides a clear framework to ensure pharmacists can be confident to authorise pharmacy technicians to carry out, or supervise others carrying out, activities while maintaining patient and public safety.

The change in the legislative framework will result in the development of new training opportunities which will support pharmacy technicians to prepare for these new roles.

Pharmacist and pharmacy technician responses

Of the individuals who responded, there was a clear split between pharmacists, many of whom opposed the changes, and pharmacy technicians who overwhelmingly supported them. Where concerns were raised, these generally related to the level of initial education and training required for pharmacy technicians and whether it was sufficient to take on these additional roles and responsibilities, and whether by extension this led to potential risks to patient safety. Further concerns were raised about:

- who (pharmacist or pharmacy technician) is accountable if things go wrong
- fears that employers would exploit the changes
- concerns the proposals may lead to removal of pharmacists from pharmacies by allowing pharmacists to remotely supervise a pharmacy to the detriment of patients' access to opportunistic clinical advice

Many of these concerns have been long held within parts of the pharmacy profession. The UK government and devolved governments are clear that we want to improve access to pharmacists in pharmacies. The introduction of clinical services in all 4 nations demonstrates the commitment to better use the expertise, skills and accessibility of pharmacists in community pharmacies. The consultation document was also clear that the proposals do not enable remote supervision or change the legal requirement that a responsible pharmacist must be signed in at a registered premises when these activities are taking place and when open to the public.

Many of the concerns raised by respondents related to matters that are beyond the scope of government legislation and instead related to practice matters that will determine how these legislative changes are implemented. For example, there were clear views expressed that pharmacists and pharmacy technicians should work within their competence and should have the ability to say no if an authorisation is not professionally appropriate. Whether to authorise pharmacy technicians to supervise activities within the pharmacy should be a matter for the pharmacist to decide, based on the particular

circumstances in their pharmacy on any given day, and informed by professional standards and guidance. This is an important principle, but not one that can be defined in government legislation, which cannot consider the many different scenarios that occur in daily practice. The purpose of the government's legislation is to set the framework - how the framework is applied will be a matter for the professions and their regulators.

Education and training

Matters relating to education and training, professional standards and guidance on what is professionally appropriate or best practice are more appropriately set by regulators and professional bodies. GPhC and PSNI, and RPS and APTUK, have committed to developing the supporting rules, regulations, standards and guidance which will underpin how the proposed changes are implemented safely into practice. These will be subject to further consultation and we encourage all stakeholders to continue to engage with regulators and professional bodies to realise the benefits of these proposals, and ensure there are safe and effective changes to professional practice.

The consultation recognised the need for a transition period to allow pharmacy regulators and professional bodies time to set out the detail required to implement these changes safely into practice before the law comes into force.

Next steps

We have carefully reviewed the consultation responses and after reflecting on the concerns raised, we are content they can be addressed through the work we have described, which will be taken forward by regulators and professional bodies. There are therefore no matters raised at consultation that have dissuaded the policy intention. We have, however, worked with the regulators to refine and make amendments to the legal drafting to address points made in response to the consultation. Alongside this consultation response, the government has laid the revised draft legislation before Parliament and intends to proceed to enact the proposals at the earliest opportunity.

Consideration of responses to individual consultation questions

Proposal 1

The consultation proposed that the Medicines Act and the HMR be amended to enable pharmacists (should they wish) to authorise a registered pharmacy technician to carry out, or supervise another person to carry out, the preparation, assembly, dispensing, sale and supply of prescription-only medicines and prescription medicines.

Question

Do you agree or disagree with proposal 1?

Table 1: responses to the question ‘Do you agree or disagree with proposal 1?’

Respondent type	Agree (number)	Agree (%)	Disagree (number)	Disagree (%)	Neither agree nor disagree (number)	Neither agree nor disagree (%)
Organisations	154	79	30	15	10	5
Individuals	1,774	37	2,924	60	162	3

Note: percentages may not total 100 due to rounding.

Feedback from responses

A total of 79% of the organisations who responded to the consultation agreed with the proposal to enable pharmacists to authorise a registered pharmacy technician, including the main representative bodies for pharmacists and pharmacy technicians.

However, only 37% of people responding as individuals agreed. There was a stark difference between the responses of the 2 pharmacy professions - 76% of pharmacists disagreed whereas 88% of pharmacy technicians agreed. The majority of those who disagreed felt the proposals went too far and were too enabling, but some also disagreed as they consider the proposals did not go far enough. Most respondents did not provide additional comments, so it is difficult to contextualise their responses.

The main themes mentioned by those who supported the proposal were based around:

- improved efficiency
- the development of the profession
- improved access to pharmacists
- patient benefit and patient safety

When discussing efficiency, respondents made points about tasks being undertaken by the most appropriate regulated professional, allowing for greater use of skills mix and

improving access to pharmacists by allowing more time for delivering clinical services. Points around development of the profession included:

- the ability to maximise the profession’s potential and contribution
- allowing pharmacy technicians to work to their full scope of practice
- making the career more appealing, helping to recruit and retain skilled staff

Some who agreed did note the need to prevent the new flexibilities being misused. They wanted to ensure the decision to authorise should rest with the pharmacist who would otherwise be responsible for carrying out or supervising the transaction, and not be imposed by a body corporate, superintendent pharmacist or chief pharmacist.

Some who agreed suggested that post-registration training should be made available to upskill the current workforce where needed, that authorisation should be a 2-way process and neither a pharmacist nor pharmacy technician should be forced to give or receive an authorisation. Some highlighted that pharmacy technicians should receive appropriate remuneration for the added responsibility.

Some who agreed had caveats (for example, agree, if the right to authorise is limited to the responsible pharmacist in a community pharmacy), but mostly these conditions related to practice matters that will be considered in the next phase of this work.

The main themes mentioned by those who disagreed with the proposal were based around pharmacy technician training, issues around who is accountable if something goes wrong, fear that these measures would be exploited by employers, and sought clarity as to how these changes would be implemented in practice.

Many pharmacists responding expressed concern that this legislation was trying to replace them with pharmacy technicians, and they emphasised the difference in initial training undergone by a pharmacist compared with a pharmacy technician. By far the most common theme was concern as to whether pharmacy technicians have the requisite training to take on the additional responsibility, particularly those pharmacy technicians who had been registered through the 'grandparent' clause when pharmacy technicians became a registered profession in 2011. Commonly, those who raised this point said it may compromise patient safety. Many pharmacists who disagreed referenced the different levels of training undertaken by pharmacists (level 7 master’s degree) compared with pharmacy technicians (level 3 diploma). Commonly, this accompanied a fear that this was a move to replace pharmacists with pharmacy technicians as a cost-cutting measure.

Many who disagreed did so on the basis that there were practice matters relating to how these measures would be implemented that required further clarification. Some who

selected ‘disagree’ noted in free text that they actually agreed but listed certain conditions to their agreement - for example:

- how record keeping would work
- who should be able to authorise across different settings
- the specifics of who is competent to supervise activities that would otherwise be supervised by a pharmacist

A common theme preventing pharmacists from agreeing was the concern that they would be held accountable for the mistakes of others who they had authorised. There were also concerns that these measures would increase the cost of indemnity insurance.

Many who disagreed had misunderstood or mistrusted the intent behind the proposals. Some had misinterpreted these changes as removing the pharmacist from carrying out a clinical check. Another common misinterpretation was that this is a move towards allowing remote supervision and enabling one pharmacist to supervise many pharmacies being run by pharmacy technicians.

Some who disagreed did so because they did not believe these measures went far enough and they should be made more enabling. For example, some thought that pharmacy technicians should be able to carry out or supervise the dispensing process without having to be supervised or authorised by a pharmacist.

Our response

The UK government and the devolved governments are committed to taking forward the proposal to allow a pharmacist to authorise a pharmacy technician to undertake or supervise another person to carry out the preparation, assembly, dispensing, sale and supply of prescription-only medicines and ‘pharmacy medicines’.

The need to reform supervision legislation has been a subject of debate for many years. We are extremely grateful to the pharmacy sector which, particularly through the Pharmacy Supervision Practice Group (a group of community pharmacy, pharmacist, and pharmacy technician representative organisations), has engaged collaboratively and constructively with these proposals. They have indicated in their consultation responses that they agree we should take this proposal forward. The Pharmacy Defence Association (PDA) and the National Pharmacy Association (NPA) selected to ‘neither agree nor disagree’ with the proposal. However, PDA have been clear they broadly support the concept of authorisation, but did not want to give full agreement until they see details on the regulatory phase to follow. NPA raised some professional practice issues in their response that had concerned their members - following reassurance that these issues

would be covered off at the next phase of the process, they also agree that they want the legislative phase to progress.

We acknowledge the concerns and apprehension expressed by individual pharmacists who responded to the consultation. They can be reassured the proposed changes are enabling but are not mandatory. Any pharmacist who does not want to authorise a pharmacy technician to supervise activities in the pharmacy has the option not to and can continue to be responsible for supervision of those activities as they are now. We believe that as this work progresses and regulators set out in more detail how these changes will be implemented in practice, most pharmacists will not only be prepared to work in the new ways these proposals enable, but will embrace the better use of skill mix as a means of allowing them to take on more clinical roles. In turn, this is expected to improve career progression and job satisfaction for the whole pharmacy team, leading to benefits for their patients.

We understand that many who disagreed with this proposal cited differences in the training of pharmacy technicians. Pharmacy technicians undertake initial education and training as defined by the regulator and are required to work within their own competence. Regardless of their route to registration, all pharmacy technicians are trained to use their professional judgement to refer to a pharmacist when performing a particular task beyond their scope of practice. Like pharmacists, pharmacy technicians can access post-registration education and training to support expanding their scope of practice and it is anticipated that the legislative change will create new training opportunities for pharmacy technicians. As with any change, relevant experience and qualifications need to be considered to ensure pharmacy technicians are not expected or pressured to work beyond their scope of practice. Professional standards, being developed by GPhC, will include appropriate references to this - for example, in setting standards for chief pharmacists. This will be reflected in future work by PSNI in due course.

In response to pharmacists who were concerned that this reform is a move to replace them with pharmacy technicians, this is not what changing supervision legislation will achieve. This work is about optimising how the complementary roles work together. All community pharmacies will still require a responsible pharmacist by law. As detailed in workforce plans across the UK, we want to grow the number of pharmacists and pharmacy technicians - not grow one workforce at the expense of the other.

We acknowledge that many individuals wanted more detail regarding practice matters and clarity on how these proposals will be implemented in practice before they supported legislation being changed. This detail does not come at the legislative phase. Government legislation sets the broad framework with the detail set out and consulted upon by the pharmacy regulators and professional bodies. This includes but is not limited to:

- new standards for superintendent pharmacists and responsible pharmacists

- updating the Royal Pharmaceutical Society of Great Britain (RPSGB - the precursor to RPS and GPhC) interim guidance for pharmacist supervision and private consultation (December 2005)

- updating the Quality Assurance of Aseptic Preparative Services (QAAPS) Standards

The implementation phase will therefore provide further opportunity for individuals to help shape these reforms.

We agree with GPhC that clarity of accountability is the fundamental element which will provide confidence to the public, pharmacists, pharmacy technicians and other pharmacy staff that these changes maintain and enhance public safety. Pharmacists and pharmacy technicians are both professionally accountable for the actions they take and the decisions they make. All healthcare professionals are also accountable to the criminal and civil courts to make sure their activities meet legal requirements. Regulatory standards in conjunction with legislation are required to give more clarity on accountability, meaning the next phase of this work is critical to ensure both pharmacists and pharmacy technicians feel confident acting under these changes.

Many pharmacists responding to the consultation disagreed with proposal 1, as they saw it as a move to reduce the number of pharmacists by replacing them with pharmacy technicians. Governments across the UK have been clear that the opposite is the desired outcome. The aim is not to have fewer pharmacists, the aim is to train more and to continue to grow the role they play in delivering clinical services and providing healthcare to the populations they serve. There is no intention to replace pharmacists with pharmacy technicians. The aim is to optimise how the pharmacy workforce works together and complements each other’s skill set, building capacity in the sector to take on enhanced roles.

We acknowledge some concerns that the low number of pharmacy technicians currently practising in community pharmacy may limit the initial implementation of these changes into practice. Changing supervision aims to support better use of the pharmacy technician workforce and encourage role development to make the employment of pharmacy technicians in the community more attractive for employers.

In England, the government will publish a new 10-year workforce plan that will support the delivery of the 10 Year Health Plan. This will ensure the NHS has the right people, in the right places, with the right skills to deliver the care patients need when they need it.

To support delivery of these commitments, NHS England has launched the Community Pharmacy Technician Apprenticeship Programme, which provided funding for:

- 530 pre-registration trainee pharmacy technicians working in community pharmacy across England in the academic year 2024 to 2025

- 525 pre-registration trainee pharmacy technicians working in community pharmacy across England planned for the academic year 2025 to 2026

- 1,764 pre-registration trainee pharmacy technician training places in NHS trusts across the 2-year programme

In addition, 840 training places for the community pharmacy technicians course 'Advancing Your Role' and 100 places for 'Accuracy Checking Pharmacy Technicians' were commissioned in the 2024 to 2025 academic year with similar numbers planned again for the 2025 to 2026 academic year. These will be provided through the Centre for Postgraduate Pharmacy Education (CPPE).

Alongside this, NHS England is working with partners to develop a UK post-registration curriculum and assessment programme for pharmacy technicians to underpin the work previously commissioned by Health Education and Improvement Wales (HEIW).

This supports the vision to develop the role of pharmacy technicians to practise more autonomously as competent and confident registered healthcare professionals.

In Northern Ireland, implementation of the Department of Health's Pharmacy Workforce Review and Community Pharmacy Strategic Plan 2030 will ensure that the pharmacy workforce will have the capacity and capability to fully support health service transformation in the coming years. A pharmacy technician regulation and development project has been established to:

- introduce the necessary changes to policy and legislation to enable the regulation and development of pharmacy technicians in Northern Ireland by April 2027

- ensure the availability of appropriate levels of education for pharmacy technicians to meet projected workforce demands

This commitment is published in the Department of Health Northern Ireland's Health and Social Care NI - Three Year Plan.

In Wales, the Strategic Pharmacy Workforce Plan was launched in summer 2023 by HEIW. The plan commits to providing a variety of training opportunities for both pre-registration and post-registration pharmacy technicians, including level 3 pre-registration pharmacy technician modern apprenticeships and level 4 programmes of learning and enhanced learning including accredited checking for pharmacy technicians (ACPT) and medicines management programmes. In addition, HEIW has commissioned APTUK to

deliver the first phase of the development of the career pathway describing the future roles of pharmacy technicians.

In Scotland, aligned with a national strategic workforce plan, the chief pharmaceutical officer has established a national pharmacy workforce forum to look at the workforce challenges, bringing together stakeholders from pharmacy education and pharmacy service provision to set a strategic workforce plan for the profession. A main priority will be building a sustainable workforce with the right skills and competencies to support the delivery of pharmacy services.

Changes to the draft statutory instrument post consultation

Authorisations given orally

Several responses asked for the removal of provisions that allow an authorisation to be given orally. This amendment would require all authorisations to be in writing. This would remove some of the flexibility pharmacists will have to lawfully authorise and delegate tasks - for example, in an emergency situation not covered by standard operating procedures (SOPs).

The main rationale provided for wanting removal of authorisations given orally was concerns around the difficulty of establishing accountability. We agree that establishing accountability where an authorisation is given is important, for both the authoriser and the person being authorised. Such decisions should be documented under SOPs or in separate documentation within a specified time of the authorisation. We consider that whether an authorisation is given orally or in writing is separate to whether the authorisation is documented, and is a matter for professional regulation rather than the criminal law framework.

Having carefully considered the responses, we are proposing to retain the flexibility for an authorisation to be given orally or in writing. However, we intend to amend the Pharmacy Order 2010 (and equivalent legislation in Northern Ireland) to make clear that the standards of conduct, ethics and performance could include descriptions of the professional responsibilities that pharmacists are to have for documenting authorisations given orally.

Professional accountability when giving an authorisation

There has, we acknowledge, been concern from respondents that a superintendent pharmacist, perhaps across many pharmacies, could override the responsible pharmacist and authorise pharmacy technicians remotely. Our view is that this type of delegation would not be professionally appropriate, and therefore professional regulation and standards is where the risk of this should be managed. We are therefore proposing to amend the Pharmacy Order 2010 (and equivalent legislation in Northern Ireland) to draw a

clear line linking the new provisions with professional standards, allowing the regulators to describe in more detail who is professionally appropriate and patient safety considerations to take account of when making that decision. This also helps make it clear that the authorising pharmacist role is legally distinct from the responsible pharmacist and superintendent pharmacist roles, although in practice all 3 roles could be fulfilled by a single person in a retail setting.

Proposal 2

Proposal 2 will enable a pharmacist to authorise any member of the pharmacy team to hand out checked and bagged prescriptions to patients or patient representatives in the absence of the pharmacist. This will align the physical pharmacy premises with current practice for home delivery, locker box and other delivery services.

Question

Do you agree or disagree with proposal 2?

Table 2: responses to the question ‘Do you agree or disagree with proposal 2?’

Respondent type	Agree (number)	Agree (%)	Disagree (number)	Disagree (%)	Neither agree nor disagree (number)	Neither agree nor disagree (%)
Organisations	157	81	22	11	14	7
Individuals	2,610	54	1,847	38	402	8

Note: percentages may not total 100 due to rounding.

Feedback from responses

A total of 81% of organisations who responded to the consultation agreed with the proposal to enable handing out checked and bagged prescriptions to patients in the absence of the pharmacist. Eleven per cent of organisations disagreed, while 7% selected ‘neither agree nor disagree’. Fifty-four per cent of people who responded to the consultation as individuals also agreed, 38% disagreed and 8% stated they neither agreed nor disagreed. Most respondents did not provide additional comments.

The main themes mentioned by those who supported the proposal were based around improved efficiency, better use of skill mix of the whole pharmacy team, and benefits resulting from improved access to medicines by aligning the practice in physical pharmacies with home delivery and other collection services.

The main point referenced by those who disagreed was concern about lost opportunities to counsel and educate patients about their medicines. They questioned whether pharmacy technicians currently have adequate training to take on the role and wanted more detail on how training would be improved. A small number of respondents were concerned that handing-out errors may increase if staff are not appropriately trained.

There was also some misunderstanding that a pharmacist will no longer be required to do the clinical check, and some wanted more details on how this proposal will be implemented, including how these types of authorisations will be recorded, how long they'll last and who can cancel or override an authorisation.

Our response

Given the overwhelming support from organisations representing the sector and strong support from individuals, we are committed to taking forward the proposal to allow checked and bagged medicines to be handed out in the temporary absence of a pharmacist. GPhC and PSNI have both confirmed that as the regulators they will provide details about the implementation of this legislation in practice.

Counselling and education of patients about their medications remains an important aspect of patient care provided from pharmacies. Pharmacists and pharmacy owners should continue to ensure that any member of the pharmacy team authorised to hand out medication to patients in their absence has the appropriate skills to carry out such tasks. Pharmacies should also ensure that they have procedures in place should a patient specifically request advice from a pharmacist or if a patient presents with information requiring consultation with a pharmacist. As noted in the consultation document, we also expect that pharmacy SOPs and sale of medicines protocols will need to include clear instructions on the conditions under which a sale or supply should not go ahead and when a discussion between the patient and pharmacist is warranted.

During the consultation, we were notified by both PDA and NPA that the words 'a pharmacist anywhere in the UK' explaining this proposal in the explanatory note at the end of the draft statutory instrument had raised concern among their membership. Their membership were concerned that this could be interpreted as a pharmacist anywhere in the UK remotely authorising someone who could also be based anywhere.

Extract from the explanatory note:

> Additionally, if a prescription-only or pharmacy medicine has been dispensed and is ready for sale or supply at or from a registered pharmacy, a pharmacist anywhere in the United Kingdom will be able to authorise any member of the pharmacy staff to undertake the final supply of that medicine in the pharmacist's absence - or where the pharmacist is treated as being absent because they are unavailable or not in a position to intervene (for example, because they are providing clinical services to a patient) (article 7(4)).

The text 'a pharmacist anywhere in the UK' is intended to indicate the territorial extent of this new provision and not imply any form of remote supervision. Proposal 2 (unlike proposals 1 and 3) will apply in Northern Ireland as the authorisation can be to non-registered members of staff. Given that this could be open to misinterpretation, we have made drafting changes following the consultation to make this absolutely clear.

For the avoidance of doubt, nothing in these proposals represents a move towards remote supervision. The presence of a pharmacist in a registered pharmacy as the default position remains the standard patients and the public expect and is enshrined in primary legislation.

Proposal 3

Proposal 3 is to allow a registered pharmacy technician to be responsible for a hospital aseptic facility in the same way that a pharmacist is under the current law.

Question

Do you agree or disagree with proposal 3?

Table 3: responses to the question 'Do you agree or disagree with proposal 3?'

Respondent type	Agree (number)	Agree (%)	Disagree (number)	Disagree (%)	Neither agree nor disagree (number)	Neither agree nor disagree (%)
Organisations	106	55	42	22	46	24
Individuals	1,424	29	2,554	53	882	18

Note: percentages may not total 100 due to rounding.

Feedback from responses

Fifty-five per cent of organisations who responded to the consultation agreed with this proposal, 20% disagreed, while 24% neither agreed nor disagreed. If we look at just the respondents who we could identify as NHS secondary care organisations (for example, NHS trusts and health boards), 87% (41 out of 47) agreed.

The primary reason for selecting ‘neither agree nor disagree’ was that an organisation that represented community pharmacy considered this part of the consultation was ‘out of scope’.

Fifty-three per cent of individuals disagreed, 29% agreed, while 18% neither agreed nor disagreed (again, commonly as they considered this part of the consultation was out of their field of expertise as they were based in community pharmacy). Most respondents did not provide additional comments.

The main point referenced by those who supported this proposal was that there are some suitably qualified and experienced pharmacy technicians ideally positioned for these roles who should not be blocked by law from supervising these facilities. Other main themes were that:

- this would help alleviate some of the workforce pressures facing hospital aseptic services

- this would provide more opportunities for development of the pharmacy technician profession

- a larger workforce would ultimately benefit the often seriously ill patients who rely on these services

In common with responses to proposals 1 and 2, a primary feature of responses from those who did not agree with the proposal was whether pharmacy technicians have the requisite training to take on these roles. Issues around accountability if something goes wrong and requests for clarity as to how these changes would be implemented in practice also featured commonly in responses. Themes unique to proposal 3 were:

- a request to run a separate consultation solely focused on hospital aseptic services, as respondents felt this proposal alone would not solve the workforce issues facing hospital aseptic services

- a view that this sector is so different to community pharmacy it should be considered separately

There was also some criticism that proposal 3 was the most enabling proposal in the consultation yet was targeted at an area of particularly high risk both in terms of the operation of hospital aseptic facilities and the medicines they prepare. Respondents, both who were in favour and who opposed the changes, were also critical that the flexibilities were being extended only to pharmacy technicians and not others (for example, science manufacturing technicians) who are increasingly being employed in hospital aseptic facilities and whose inclusion would support futureproofing the proposals.

When discussing training, those who disagreed noted that the pharmacy technician training results in a level 3 diploma, while a pharmacist is trained to a level 7 master's degree. They also reported concerns about the level of practical experience in medicines manufacturing and aseptic services in pharmacist and pharmacy technician initial education and training. Respondents acknowledged that pharmacy technicians working in these facilities have excellent technical skills, but a lack of clinical training was noted as a primary reason they should not take overall responsibility for the facility.

Some were critical that the proposals did not set out the level of experience and post-registration qualification required by pharmacy technicians. In relation to the requirement for the hospital aseptic facility to be overseen by a chief pharmacist (or someone fulfilling the statutory functions of a chief pharmacist) in order to use the flexibility, some questioned whether a chief pharmacist was too far removed to take overall responsibility for the safe and effective running of hospital aseptic services.

When discussing the need for a separate consultation, those who disagreed with proposal 2 asserted that the risks associated with dispensing a licensed medicine in a dispensary setting are fundamentally different to those associated with the preparation and aseptic dispensing. Commonly, it was noted that these measures alone would not solve workforce issues in hospital aseptic services and broader reform dedicated solely on these services (both licensed and section 10 aseptic production) is required.

Following the consultation, further engagement was undertaken with representatives of the committees and groups including those spanning:

- quality assurance
- pharmaceutical production
- aseptic services
- advanced therapy medicinal products
- education and training

On 19 April 2024 a meeting was held with stakeholders from across the technical services and quality assurance sectors. These groups have indicated they are now supportive of the overall objectives of the proposed legislative changes and have made detailed recommendations on a set of principles to consider when implementing these changes in practice. Those recommendations have been considered when forming the government's response to this proposal and will continue to inform the next phase of this work.

Our response

The UK and devolved governments are committed to building greater resilience in the supply of aseptically prepared medicines and advanced therapies, as well as increasing the capacity of hospital aseptic facilities to support the availability of clinical trial medications, allowing patients to have timely access to new treatments.

While proposal 1 (authorisation) and proposal 2 (checked and bagged) received strong support from the sector, proposal 3 received more mixed feedback - with strong views opposing the proposal from certain main groups. There were also strong views supporting the proposal from secondary care organisations and from individual members of groups whose collective response had been to oppose the proposals. This is indicative of the wide-ranging views in this area. Together with NHS England, we have focused post-consultation stakeholder engagement on this element of the proposals to better understand the views and reasoning of individuals and groups who opposed the change.

With regards to the request that hospital aseptic services are considered separately to the other proposals in this consultation, we recognise the production of aseptic medicines in hospitals and the dispensing of medicines in community pharmacy are very different activities taking place in very different settings. Despite the clear differences in practice, both are enabled by the same primary and secondary legislative powers defining supervision. While the 3 proposals form part of a single consultation it does not mean the legislative, regulatory and professional practice changes need to be the same for each proposal. The proposals are clearly distinguished from one another with the opportunity to respond in different ways to each, and to allow tailored approaches to delivering the policy intention recognising the very different circumstances covered by the 3 proposals.

We acknowledge that there are workforce issues facing aseptic production. Many experienced staff are reaching retirement and as pharmacists' roles and education and training has become more focused on clinical practice, the next generation of pharmacists available to replenish the current expertise may include fewer with the skills or interest to work in this area at the point of registration.

Advances in medicine mean the importance of aseptic preparation is increasing and we are dedicated to reversing the decline in the available workforce by making pharmacy

aseptic production an area where pharmacists, pharmacy technicians and non-pharmacy life sciences graduates want to work.

We recognise that the legislative changes proposed as part of this reform form only part of a solution. In England, the NHS England Infusions and Special Medicines Programme, commissioned by DHSC in response to the report Transforming NHS pharmacy aseptic services in England, is overseeing a broader plan for the pharmacy technical services workforce and training pathways. Similar work - for example, the Transforming Access to Medicines (TrAMs) programme in Wales and the Department of Health's Pharmacy Aseptic Services Review in Northern Ireland - is ongoing in other parts of the UK.

These programmes include the wider use of science manufacturing technicians and clinical (pharmaceutical) scientists and/or healthcare scientists in aseptic production. The proposed changes to enable pharmacy technicians to supervise hospital aseptic facilities is an important element of this broader workforce plan and will pave the way for consideration of future changes to other legislation to enable appropriate professional groups to undertake these roles. The transformation of pharmacy aseptic services was outside the scope of this consultation, which was focused on the Medicines Act in relation to the professional regulation of pharmacists and pharmacy technicians.

With regards to whether pharmacy technicians have adequate clinical knowledge to take on these roles, section 10 medicines assembly must be done in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber. Pharmacists have a critical role in the production of this specification where their clinical and pharmaceutical knowledge helps ensure not only the clinical appropriateness of treatment but also that the specification is formulated in a way which meets an individual patient's needs. Once the specification has been agreed, the assembly of the product can be carried out in accordance with the procedures in place in the hospital aseptic unit.

Currently, in many hospital aseptic facilities a pharmacist may be carrying out both the clinical verification of the prescription and supervising technical preparation and assembly in the aseptic unit. This is a consequence of the current legislative framework which constrains pharmacists' ability to maximise the time they spend using their clinical skills. There is no reason why the clinical and supervision of the technical parts of the process cannot be separated as has been done in hospital dispensaries that are overseen by pharmacy technicians. This would be subject to pharmacy technicians having demonstrated their competence to supervise the aseptic preparation of medicines.

Separating clinical and technical processes will enable pharmacists to be released for greater input to clinical activity. There will, of course, continue to be a requirement for pharmacists and pharmacy technicians to work together, particularly where non-routine specifications are ordered. It will take time for hospitals to change business processes to

benefit from these proposals, and as with proposals 1 and 2, the change is enabling and not being mandated. It will be for each hospital aseptic facility to decide whether, when, and to what extent it uses the additional flexibility provided by the change.

With regards to initial education and training, it is clear that neither pre-registration pharmacy technician nor pharmacist undergraduate and foundation training adequately equips new registrants with the expertise required to oversee a hospital aseptic facility. Both pharmacists and pharmacy technicians are expected to have undertaken additional, post-registration specialist training and acquired further relevant experience after registration before being able to effectively supervise hospital aseptic facilities. The required competencies, knowledge and training for pharmacy technicians and pharmacists supervising hospital aseptic facilities will be different, recognising the different starting positions provided by their respective initial education and training programmes. This cannot be set out in government legislation. It can, however, be set more appropriately in regulatory and professional standards. We agree with respondents that there is a need to review professional standards in this area to ensure they authoritatively describe the qualifications, competence and experience required by pharmacists and pharmacy technicians supervising hospital aseptic facilities to provide continued assurance regarding the quality of unlicensed pharmacy aseptic facilities within the NHS.

Enabling appropriately trained and experienced pharmacy technicians, in addition to pharmacists, to supervise hospital aseptic services will improve the use of skill mix within secondary care pharmacy teams - ultimately this will have benefits for patients. The changes proposed also allow for the development of the role of pharmacy technicians as registered healthcare professionals. Like pharmacists working in hospital aseptic services, many pharmacy technicians have already undertaken post-registration qualifications including up to master’s level in pharmaceutical technology and quality assurance (PTQA). This type of additional training provides a solid foundation from which pharmacy technicians could in the future demonstrate the competencies required to take on these roles.

With regards to whether the proposal is too enabling when it comes to the production of high-risk medicines in hospital aseptic facilities, it is not uncommon for pharmacy technicians to be among the most experienced pharmacy professionals working in these facilities. Enabling experienced and competent professionals, be they pharmacists or pharmacy technicians, to supervise these facilities is intended to increase the safety and resilience of services producing these medicines by recognising it is an individual’s knowledge and competency which determines their suitability for the role and not simply which profession they belong to.

Under the proposal, a chief pharmacist would retain overall responsibility for the safe and effective running of a hospital’s aseptic facilities. Chief pharmacists will be accountable for ensuring the appropriate governance arrangements are in place to support supervision by

pharmacy technicians. The chief pharmacist should be no further removed from these facilities than from any other pharmacy service for which they are accountable. Chief pharmacists already establish governance processes for pharmacy and medicines that extend across all of their departments and services, and more broadly in their hospitals. This includes ensuring the pharmacy workforce has the right skills, knowledge and experience, and delegating responsibility to appropriately competent individuals, to deliver safe and effective pharmacy services.

Chief pharmacists use the following, within an overall governance structure, to provide assurance of the quality and safety of the services provided to organisations:

- policies
- procedures
- job descriptions
- person specifications
- competency training programmes
- quality management systems
- performance monitoring
- risk assessment and management
- regulatory requirements and inspection reports
- professional guidance

These systems will continue to form part of the robust governance arrangements supporting the delivery of high-quality hospital aseptic production and will be reinforced by publication of the standards for chief pharmacists developed by GPhC.

We acknowledge the concerns raised by some respondents spanning quality assurance, pharmaceutical production, aseptic services, advanced therapy medicinal products, education and training and others, that these changes need to be supported by revised professional standards for aseptic services. As outlined in the consultation, we expect these standards to describe how supervision by a pharmacy technician can safely operate in practice, including specifying the appropriate knowledge and the competencies required for the supervising and ‘accountable’ pharmacist and pharmacy technician.

Standards in this area have been in place since 2016 and are widely regarded as needing review. NHS England, NHS Wales and NHS Scotland have jointly commissioned RPS to update the QAAPS Standards. RPS will review the standards, anticipating the changes to allow a pharmacy technician to supervise hospital aseptic facilities. These standards will be subject to separate consultation by RPS.

The likely time required to undertake this work will be reflected when setting a commencement date for the regulations.

We have considered the views of respondents who agreed that pharmacy technicians could supervise activities in a hospital aseptic facility but only when authorised by a pharmacist. We agree that in some pharmacy services this may be the preferred arrangement, particularly in the short term. However, work is planned to define the competencies required by pharmacy technicians supervising hospital aseptic facilities, to update the professional standards specific to aseptic services and the responsibilities of chief pharmacists. In view of this, we consider it appropriate to treat hospital aseptic services as a special case, distinct from the other proposals that apply generally to pharmacy technicians.

In contrast to the general position, we consider the supporting measures will over time enable more pharmacy technicians, as some already have, to acquire the necessary knowledge, experience and competency to supervise hospital aseptic facilities without needing pharmacist authorisation. This is provided that it is within the governance arrangements set out by the hospital's chief pharmacist.

For these reasons, we will take forward proposal 3 as originally intended, while continuing to engage with experts in this field to ensure the appropriate supporting measures are put in place.

'At or from'

We proposed that regulation 220 of HMR is brought into line with the changes already made to other legislation concerning the supply of medicines 'at or from' a registered pharmacy premises. This is to better reflect current practice, particularly in the provision of delivery services from a registered pharmacy premises.

Question

Do you agree or disagree with this proposal?

Table 4: responses to the question 'Do you agree or disagree with this proposal?'

Respondent type	Agree (number)	Agree (%)	Disagree (number)	Disagree (%)	Neither agree nor disagree (number)	Neither agree nor disagree (%)
Organisations	152	79	15	8	25	13
Individuals	2,033	42	1,604	33	1,224	25

Note: percentages may not total 100 due to rounding.

Feedback from responses

Seventy-nine per cent of organisations who responded to the consultation agreed with the proposal to amend regulation 220 of HMR in line with the changes already made to other legislation concerning the supply of medicines ‘at or from’ a registered pharmacy premises. This notably includes agreement from the Pharmacy Law and Ethics Association. Eight per cent of organisations disagreed, while 13% neither agreed nor disagreed. Of those who agreed, most respondents did not provide comments. Where comments were made in support, these reflected the need to align the legislation and that collection and delivery services from pharmacies have been in place for many decades with the approval of pharmacy professional and regulatory bodies.

Of those who disagreed, the majority did not provide comments. Of those who did provide comments, these generally did not relate to the question or there was some misunderstanding. Some respondents did, however, have concerns that there may be unintended consequences that were not fully explored in the consultation document.

Forty-two per cent of individuals agreed, 33% disagreed and 25% neither agreed nor disagreed. Of those who agreed, similar reasons were given. Of those who disagreed, comments primarily did not relate to the question, or the question had been misunderstood. For example, many responses used this question to raise concerns around the Community Pharmacy Contractual Framework, funding and practice matters related to previous questions.

Our response

The UK and devolved governments are content to amend regulation 220 of HMR to bring this into line with the changes already made to other legislation concerning the supply of medicines ‘at or from’ a registered pharmacy premises. This reflects current practice and support patients in accessing medicines in the most appropriate and convenient way.

This is a straightforward alignment of current legislation which reflects changes already made to the Medicines Act by the Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 (2022 order). These are minor changes clarifying that medicines may be supplied from, as well as at, pharmacy premises. For example, in the context of home deliveries, the 2022 order makes it clear that a delivery driver is no longer considered a representative of a patient, and the responsible pharmacist is responsible for the supply until the medicine is handed to the patient. It should be noted that locker boxes and other automated collection services still require registering separately to the pharmacy business, and no change to practice is required.

Legislative barriers

Question

Do you think there are any other barriers to modernising pharmaceutical practice in government legislation that we should consult on removing in the future?

Feedback from responses

A total of 1,019 responses were received to this question. Where responses provided detail, they echoed comments previously made in response to proposals 1 to 3.

Currently, the preparation and assembly of medicines can only occur when a responsible pharmacist is signed in at the pharmacy. Several responses echoed earlier calls from the Community Pharmacy Supervision Practice Group that preparation and assembly should be allowed to occur under the supervision of a superintendent pharmacist in a registered pharmacy that is closed with no responsible pharmacist signed in.

Other issues raised include:

- updating of the ‘general sales list’ as referenced in sections 71, 72A and 72AA of the Medicines Act. There is a general sale list, but nothing has been added to it since 2001. The Medicines Act should provide references to ‘a general sale list’ including medicines that are subject to general sale as defined in regulation 5 of HMR

- extension of proposal 3 to allow other healthcare professionals such as science manufacturing technicians and clinical scientists to oversee a hospital aseptic facility

- consequential changes to regulation 36 of The Medicines for Human Use (Clinical Trials) Regulations 2004, to reflect the changes in proposal 1 and 3 that assembly of investigational medicinal products will in future be able to be undertaken under the supervision of either a pharmacist or pharmacy technician

- original pack dispensing - calls for amendments to authorise the supply to be made by or under the supervision of a pharmacy technician

- hub and spoke dispensing - calls for amendments to future proposals to ensure the new route of authorisation is permitted in these dispensing models

Our response

We thank respondents who have taken the time to provide answers to this question. The government strives to create and deliver policy that meets the demands of a fast-paced and evolving pharmacy profession. The ideas generated will be carefully considered and inform future policy development.

The government will take forward consequential amendments to the Medicines for Human Use (Clinical Trials) Regulations 2004 and the HMR in relation to original pack dispensing and hub and spoke dispensing at the same time as the core measures subject to this consultation. Further details are provided below alongside all consequential amendments being taken forward.

With regards to the preparation and assembly of medicines under the supervision of a superintendent pharmacist when the responsible pharmacist is not signed in, we agree this proposal merits further consideration, but it cannot be taken forward without further consultation, meaning it cannot be progressed as part of these reforms.

With regards to other professionals being included within the scope of proposal 3, allowing them to supervise hospital aseptic facilities, this is addressed above under proposal 3. Any changes to the current law to allow science manufacturing technicians, clinical scientists or other suitably qualified healthcare professionals to be responsible for a hospital aseptic facility would require separate review and appropriate public consultation. This means this cannot be progressed as part of these reforms and is not part of the draft legislation laid before Parliament.

Impact assessment

Question

If you have any further information to inform the consultation-stage impact assessment on the costs and benefits of each option, please provide it here.

Feedback from responses

A total of 622 responses were received answering this question. The vast majority of responses did not relate to the content of the impact assessment. Of those that raised comments in relation to the impact assessment the main themes raised included:

- data on error rates
- lack of detail on the proposals for hospital aseptic facilities
- familiarisation costs - the time it takes professionals to understand the proposals
- costs of adapting pharmacy protocols and procedures
- costs of training pharmacy technicians and other pharmacy staff
- staff costs in terms of pay increases to reflect additional responsibilities

Our response

The impact assessment has been updated to make clear the impact on business, charities or voluntary bodies is zero because the legislation is permissive and therefore has no direct impact on businesses. Where businesses choose to use the new flexibilities in law, the impact is expected to have a net positive benefit. The impact assessment has also been updated to expand on the narrative relating to hospital aseptic facilities following the consultation and wider engagement with the sector. While it was not possible to monetise costs and benefits relating to hospital aseptic facilities, data obtained through the sector and NHS England provided further context to the costs and benefits identified.

Clarifications have been made to the assumption used to estimate the time taken for a pharmacist to understand the proposed changes in legislation, which assumes one hour taken. It has also now been assumed that all new pharmacy technicians will have to undergo training to be able to take on the supervisory role, meaning the ongoing cost of training is higher. The potential increase to staff costs has not been included within the impact assessment as it is assumed that any increase in staff costs would be offset by benefits to business in terms of released pharmacist time. Finally, all data has been updated to ensure the latest figures have been used within the cost-benefit analysis.

Further details of the equality impact assessment and consideration of the Secretary of State's duties under the National Health Service Act 2006 are provided in annex 2.

Draft statutory instrument

Question

If you have any further comments on any aspect of the draft statutory instrument, please provide it here.

Feedback from responses

A total of 276 responses were received answering this question. The vast majority of responses commented on other aspects of the consultation, or on matters that did not relate to the draft statutory instrument. Examples include:

- concerns around pay and conditions
- practice matters such as presence of a pharmacist, and who undertakes the clinical check of prescriptions

Of the responses relevant to the question, the main themes repeated points raised in earlier questions. These related to:

- the removal of oral 'authorisations', instead requiring all authorisations to be in writing and documented or otherwise recorded to ensure a clear audit trial
- as explored in proposal 3, changes to the statutory instrument to include other scientists and healthcare professionals and not just pharmacy technicians
- consequential changes to legislation concerning who can supply under a serious shortage protocol, and who can supervise an emergency supply of medicines
- consequential changes to regulation 37 of The Medicines for Human Use (Clinical Trials) Regulations 2004, to reflect that the assembly of an investigational medicinal product may in future be under the supervision of a pharmacist or pharmacy technician
- amendments to recent proposals on original pack dispensing which allow pharmacists to have flexibility to dispense more or less than the prescribed quantity (up to 10% more or less) if that means they can dispense in the manufacturer's original packs (original pack dispensing) to ensure they reflect that such sale or supply can be under the supervision of either a pharmacist or registered pharmacy technician
- support for a transition period, which is long enough to implement changes to professional rules, regulations and underpinning guidance
- technical drafting points in relation to the draft statutory instrument and explanatory note

Our response

Having carefully considered responses and post-consultation engagement with primary stakeholders, the draft statutory instrument has been amended and restructured to ease reading. The main changes are outlined below and the revised draft statutory instrument is published alongside this document on legislation.gov.uk.

Authorisation given orally or in writing

Several responses asked for the removal of provisions that allow an authorisation to be given orally under draft regulation 220A (authorisations given by pharmacists to registered pharmacy technicians) and draft regulation 220B (sale or supply of items dispensed by a pharmacist who is absent or treated as absent), due to concerns about lack of clear accountability. We have carefully considered the responses but will retain the provision to permit authorisations given orally. The main basis for this is that if the legislation were amended to require all authorisation to be in writing, this would remove some of the flexibility pharmacists will have to lawfully authorise and delegate tasks - for example, in an emergency situation not covered by standard operation procedures.

We do, however, agree that establishing accountability where an authorisation is given is important for both the authoriser and the person receiving the authorisation, and that such decisions should be documented under SOPs or in separate documentation in a specified time after the event. We consider that whether an authorisation is given orally or in writing is separate to whether the authorisation is documented and is a matter for professional regulation rather than the criminal law framework.

Having considered the responses, we are proposing 2 sets of linked amendments to the draft statutory instrument. Firstly, in draft regulation 220B, we are clarifying what exactly the authorisation can cover. The implicit reference is to the list of the sort of things that, in Great Britain, the authorisation given to registered pharmacy technicians under section 10 of the Medicines Act and draft regulation 220A of the HMR will be able to cover. In the consultation draft, only one item in this list was copied across (‘an authorisation that may be given subject to conditions or restrictions’), but on reflection we are proposing to copy across 3, including stating specifically that the checked and bagged authorisation can be given orally or in writing and that an authorisation may be varied or withdrawn by the pharmacist.

Secondly, we have also added amendments to the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976 - which both set out requirements for professional regulation and the role and responsibilities of the pharmacy regulators in Great Britain and Northern Ireland. The proposed changes will make clear that the regulators, when setting standards of conduct, ethics and performance, could include descriptions of the professional responsibilities that pharmacists are to have for documenting authorisations given orally.

Note the proposal is to only amend the Pharmacy (Northern Ireland) Order 1976 in relation to regulation 220B initially. If a comparison is made between draft article 48(1C) of the Pharmacy Order 2010 and draft sub-paragraph 1(1C) of schedule 3 to the Pharmacy (Northern Ireland) Order 1976, it will be apparent that the Northern Ireland provision is more limited because fewer of the new flexibilities are to apply in Northern Ireland at this time. Once pharmacy technicians become a registered profession in Northern Ireland, and

the other new flexibilities can be applied in Northern Ireland, the expectation is that article 48(1C) and sub-paragraph 1(1C) will then mirror each other.

This position has been agreed with GPhC and PSNI.

Authorisation given by 'a pharmacist'

At consultation, a primary concern raised by respondents was that the reforms could enable a superintendent pharmacist, perhaps working across many pharmacies, to override the responsible pharmacist and authorise pharmacy technicians remotely. Our view is that this type of delegation would not be professionally appropriate, and therefore the risk of this should be more appropriately managed through professional regulation and standards. We are therefore proposing to amend the Pharmacy Order 2010 and the Pharmacy (Northern Ireland) Order 1976 to draw a clear line linking the new provisions on authorisation with professional standards, allowing the regulators to describe in more detail who is professionally appropriate to authorise and/or delegate and patient safety considerations.

Other issues considered and discounted are discussed below.

Hospital aseptic facilities

The legislation being amended as a result of this consultation relates to pharmacy and pharmacy professionals. As outlined above in the legislative barriers section, any changes to allow science manufacturing technicians, clinical scientists or any other suitably qualified healthcare professionals to be responsible for a hospital aseptic facility in the same way that a pharmacist is under the current law would require a separate review and appropriate public consultation. It is therefore not possible to take forward the suggested changes under this statutory instrument.

Serious shortage protocols and emergency supply

The government is not making changes to the legal provisions concerning serious shortage protocols (regulation 226A of the HMR) or emergency supplies of medicines (as set out in regulations 224, 225 and 226 of the HMR). All these types of supply require a clinical and/or diagnostic decision, and therefore we consider it is professionally appropriate that these types of supply still rest with a pharmacist. Therefore, such supplies will continue to be supplied by or under the supervision of a pharmacist. Any consideration of adding registered pharmacy technicians to these provisions will require a separate consultation.

Consequential changes

As a result of the proposed changes to the Medicines Act and the HMR, there are a number of consequential changes required to related legislation. These changes received general support at consultation and will be taken forward to coincide with the coming into force of the changes in the draft statutory instrument. In a change to the consultation draft statutory instrument, amendments to The Medicines for Human Use (Clinical Trials) Regulations 2004 have been added, alongside changes to the HMR relating to original pack dispensing and hub and spoke dispensing. Further detail is provided below on all consequential changes.

Original pack dispensing

A number of responses called for consequential changes to the recent provisions on original pack dispensing, made under The Human Medicines (Amendment Relating to Original Pack Dispensing) (England and Wales and Scotland) Regulations 2023. We agree that it is reasonable to make consequential changes to regulation 217B of the HMR to allow the new delegation arrangements to apply to the new arrangement on original pack dispensing. Original pack dispensing gives the flexibility to dispense up to 10% more or less of a prescription-only medicine compared with the quantity prescribed, if it means pharmacists can dispense the medicine in its original manufacturer's packaging. This avoids a pharmacy needing to split original packs.

The provision is enabling but the pharmacist is not entitled to rely on it if, in applying their clinical judgement, dispensing in an original pack would negatively affect the patient's clinical treatment regimen. By amending original pack dispensing, this will mean that where a pharmacy technician is carrying out or supervising the sale or supply, the pharmacy technician will be able to dispense a medicine not in the original outer packaging - for example, a medicine that is required to be placed in a monitored dosage system, such as a dosette box.

As before, the provisions are enabling, and the legislative framework means that, going forward, a pharmacist or pharmacy technician will continue to be required to make a clinical decision - as part of a clinical check - as to the appropriateness of supplying an original manufacturer's pack rather than the exact quantity prescribed to ensure that the patient's clinical needs are met.

For similar reasons, the government is also amending regulation 217C of the HMR, concerning specific requirements for medicines containing all forms of valproate. The law is clear that valproate should always be supplied in the manufacturer's original packing except in exceptional circumstances. This amendment will mean that where a pharmacist

has authorised a pharmacy technician to do the dispensing, the pharmacy technician is under the same obligations in relation to valproate that previously applied to pharmacists.

These new arrangements will only apply in Great Britain as pharmacy technicians are not currently a regulated profession in Northern Ireland. Our aim is to apply this legislation in Northern Ireland once this is possible.

Hub and spoke

The draft statutory instrument includes amendments to the provisions expected to give effect to the new hub and spoke arrangements, as some of these provisions presuppose supervision by a pharmacist. The amendments allow for the new authorisation arrangements in proposal 1.

‘At or from’

Linked to proposals 1 and 2, the consultation proposed to change, for the whole of the UK, the reference in regulation 220 to supply needing to take place ‘on premises’ that are a registered pharmacy to ‘at or from’ such premises. This is a change that we have already made to equivalent references in the Medicines Act - in The Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022. It also reflects current practice, particularly where delivery services are used, which has led to strained readings of the legislation - including strained understandings of when supply takes place - in order to ensure that current standard practices are understood to have a proper legal base. This change is now made by The Human Medicines (Amendments Relating to Hub and Spoke Dispensing etc.) Regulations 2025, which precedes this statutory instrument.

VAT

HM Treasury and HM Revenue and Customs have confirmed that medicines dispensed by or under the supervision of a registered pharmacy technician will benefit from a zero rate of Value Added Tax (VAT), as is currently the case for medicines dispensed by or under the supervision of a registered pharmacist. This will ensure there are no financial barriers for NHS pharmacy contractors implementing these changes. HM Treasury has agreed to bring forward a statutory instrument to amend the Value Added Tax Act 1994 to ensure consequential changes to the Value Added Tax Act commence at the same time as the changes to the Medicines Act and HMR.

Controlled drugs

The Misuse of Drugs Regulations 2001 and The Misuse of Drugs Regulations (Northern Ireland) 2002 specify that a pharmacist may manufacture or compound, supply or destroy

any drugs subject to controls under schedules 2 to 5 of the regulations. This includes drugs such as morphine, codeine and pregabalin.

To implement the proposals, consequential changes to the Misuse of Drugs Regulations 2001 and the Misuse of Drugs (Safe Custody) Regulations 1973 are required to enable pharmacy technicians to undertake these activities across pharmacy settings within the scope of this consultation.

Changes to the Misuse of Drugs Regulations 2001 were included in the draft statutory instrument at consultation and will commence at the same time as the proposed changes to the Medicines Act and HMR. Changes to the Misuse of Drugs (Safe Custody) Regulations 1973 have been added to the draft statutory instrument post-consultation to ensure the proposals have full legal effect. Changes to the Misuse of Drugs Regulations (Northern Ireland) 2002 will not be required until pharmacy technicians become a registered healthcare profession in Northern Ireland.

The regulators have committed to consult the expertise of the Advisory Council on the Misuse of Drugs in implementing the necessary changes to professional standards and guidance concerning the handling and dispensing of controlled drugs under the new provisions.

Clinical trials regulations

Regulation 37 of the Medicines for Human Use (Clinical Trials) Regulations 2004 sets out that an investigational medicinal product may only be assembled by a doctor, a pharmacist or a person acting under the supervision of a pharmacist. In consultation with the Medicines and Healthcare products Regulatory Agency, this provision will be amended to reflect that the assembly of an investigational medicinal product may in future be under the supervision of a suitably qualified pharmacist or pharmacy technician.

This will mirror the provisions under new section 10A and will require a pharmacist to authorise a pharmacy technician to undertake or supervise this activity. The changes to the Medicines for Human Use (Clinical Trials) Regulations 2004 will commence at the same time as the changes to the Medicines Act and the HMR.

Transition periods

As set out at consultation stage, the government recognises the need for a transition period to allow pharmacy regulators and professional bodies time to set out the detail required to implement these changes safely into practice before the law comes into force. Consultation responses supported this approach, and a transition period will be agreed with the Privy Council.

The intention is to bring the provisions concerning checked and bagged prescriptions into force as soon as practicably possible after the final order is agreed by Parliament and the Privy Council. The rest of the provisions in the final order will have a longer transition period to allow for the drafting of regulatory standards and professional guidance to support safe implementation into practice.

NHS pharmaceutical contract regulations

England

Schedule 4, part 2 of The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 require that medicines must be ordered 'either by or under the direct supervision of a registered pharmacist'. These regulations will be reviewed in consultation with Community Pharmacy England, to ensure the regulations are aligned with the policy intent outlined in this consultation.

Wales

Schedule 5, part 2 of The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 require that medicines must be ordered 'either by or under the supervision of a registered pharmacist'. These regulations will be reviewed in consultation with Community Pharmacy Wales to ensure the regulations are aligned with the policy intent outlined in this consultation.

Scotland

Paragraph 7 of schedule 1 of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 require that the dispensing of medicines can only take place 'either by or under the direct supervision of a pharmacist'. These regulations as amended will be reviewed in consultation with Community Pharmacy Scotland, to ensure the regulations are aligned with the policy intent outlined in this consultation.

Northern Ireland

Schedule 2, part 2, paragraph 5 of the Pharmaceutical Services Regulations (Northern Ireland) 1997 require that medicines must be supplied 'either by or under the direct supervision of a pharmacist'. These regulations will be reviewed in consultation with Community Pharmacy Northern Ireland to ensure the regulations are aligned with the policy intent outlined in this consultation.

Next steps

Following consideration of the consultation responses, the UK government and devolved governments will take forward the amended draft statutory instrument.

Subject to Parliamentary time, the draft Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2025 will be debated in the Westminster Parliament in accordance with the affirmative resolution procedure.

Annex 1: breakdown of consultation respondents by profession and location

Note: percentages may not always total 100% due to rounding.

Responses to proposal 1

Figure 1: responses to proposal 1 by respondent type

Respondent type	Disagree	Neither agree nor disagree	Agree	Total
On behalf of an organisation	15%	5%	79%	99%
An individual	60%	3%	37%	100%

Figure 2: responses to proposal 1 by profession

Profession	Disagree	Neither agree nor disagree	Agree	Total
Pharmacy technician	8%	3%	88%	99%
Pharmacist	76%	3%	21%	100%

Figure 3: individual responses to proposal 1 by place of residence

Place of residence	Disagree	Neither agree nor disagree	Agree	Total
Wales	56%	5%	39%	100%

Place of residence	Disagree	Neither agree nor disagree	Agree	Total
Scotland	60%	2%	38%	100%
Northern Ireland	55%	0%	45%	100%
England	60%	3%	36%	99%

Responses to proposal 2

Figure 4: responses to proposal 2 by respondent type

Respondent type	Disagree	Neither agree nor disagree	Agree	Total
On behalf of an organisation	11%	7%	81%	99%
An individual	38%	8%	54%	100%

Figure 5: responses to proposal 2 by profession

Profession	Disagree	Neither agree nor disagree	Agree	Total
Pharmacy technician	7%	6%	87%	100%
Pharmacist	49%	9%	43%	101%

Figure 6: individual responses to proposal 2 by place of residence

Place of residence	Disagree	Neither agree nor disagree	Agree	Total
Wales	33%	12%	55%	100%
Scotland	32%	9%	59%	100%
Northern Ireland	24%	21%	55%	100%
England	39%	8%	53%	100%

Responses to proposal 3

Figure 7: responses to proposal 3 by respondent type

Respondent type	Disagree	Neither agree nor disagree	Agree	Total
On behalf of an organisation	22%	24%	55%	101%
An individual	53%	18%	29%	100%

Figure 8: responses to proposal 3 by profession

Profession	Disagree	Neither agree nor disagree	Agree	Total
Pharmacy technician	10%	15%	75%	100%
Pharmacist	65%	20%	15%	100%

Figure 9: individual responses to proposal 3 by place of residence

Place of residence	Disagree	Neither agree nor disagree	Agree	Total
Wales	43%	18%	39%	100%
Scotland	47%	26%	27%	100%
Northern Ireland	37%	18%	45%	100%
England	53%	17%	29%	99%

Annex 2: legal duties

Equality impact assessment and consideration of Secretary of State's duties under the National Health Service Act 2006.

Legal duties

The Secretary for State for Health and Social Care and the Department of Health in Northern Ireland, as part of their work on policy formation in this area and consideration of responses to the consultation, have to consider a number of important duties. In particular, their obligations under, respectively, the Equality Act 2010 and section 75 of the Northern Ireland Act 1998 - and, in the case of the Secretary of State, the Family Test and the government's environmental principles policy statement under the Environment Act 2021.

The general equality duty that is set out in the Equality Act 2010 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 Equality 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 believe that the proposals detailed here would have adverse or different impacts on individuals with protected characteristics. The proposal would support better use of the skill mix in pharmacy teams and pharmacy technicians to be responsible for certain actives in pharmacy services. More efficient and better-quality services would benefit any patient accessing pharmacy services - in the community, a hospital, a clinic or care home.

Secretary of State's duties

The National Health Service Act 2006 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 following.

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 greater use of registered pharmacy technicians will free up pharmacists' time which could be used to focus their clinical expertise on delivering patient facing services and dealing with 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 policy contributes to improvement in the quality of services through facilitating timely access to medicines. Under current legislation, medicines can only be handed out when a pharmacist is present. This can lead to delays and repeat visits which can result in poor patient experience. The ability for a pharmacist to authorise the handing out of checked and bagged prescriptions in their absence will help ensure patients receive their medicines at the right time and minimise any delay. This will contribute to better patient outcomes by better using the skill mix in pharmacies to provide additional capacity to treat patients, providing new routes for access to pharmaceutical services.

The duty as to reducing inequalities (section 1C)

The proposed legislative framework is enabling and promotes better use of the skill mix in pharmacies and more efficient services. Increasing the capacity of pharmacy services and how staff are deployed could help free capacity for clinical appointments and reduce pressures within other parts of the healthcare system.

Family Test

We have considered the impact of this policy on the Family Test, namely:

- family formation
- families going through key transitions
- ability of family members to play a full role in family life
- families before, during and after couple separation
- families most at risk of deterioration of relationship quality and breakdown

Our conclusion is that this policy will not impact on the different aspects of the Family Test.

Environmental duties

On 1 November 2023 the environmental principles policy statement (EPPS) duty came into force in relation to England, Wales and Scotland. This places a legal duty on UK ministers to have due regard to the government's EPPS when developing policy.

The EPPS sets out 5 internationally recognised environmental principles to be considered. The 5 principles work together to help create opportunities to avoid, minimise and remedy environmental damage to improve environmental protection.

The 5 principles are:

- integration - environmental protection should be integrated into the making of policy
- prevention - damage to the environment should be prevented before it has occurred and/or existing damage should be contained
- rectification at source - damage to the environment should be tackled at its origin
- polluter pays - the costs of pollution should be borne by those causing it, wherever possible
- precautionary - policymakers need to make a reasonable assessment of the environmental risk, particularly where there is a lack of scientific certainty

In considering these principles in the development of this policy, our view is that the policy proposals are aligned to the EPPS duty. Further, the proposals to allow the handing out of checked and bagged prescriptions in the absence of the pharmacist may be expected to reduce repeat visits to a pharmacy and potentially reduce patient and public travelling distances, therefore having a positive impact on congestion and pollution. The wider policy objective is to make greater use of the skill mix of pharmacy teams. This will enable the shift of care away from hospitals to deliver more clinical services closer to communities in their local pharmacy. This is expected to have a positive impact on reducing pollution and congestion.