Title: The Draft Human Medicines (Authorisation by Pharmacists and Supervision by Pharmacy Technicians) Order 2024	**Impact Assessment (IA)**
IA No: 9600	**Date:** 01/11/2023
RPC Reference No: N/A	**Stage:** Consultation
Lead department or agency: Department of Health & Social Care	**Source of intervention:** Domestic
Other departments or agencies:	**Type of measure:** Secondary legislation
	Contact for enquiries: Stephen.Knight@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: Not applicable

Cost of Preferred (or more likely) Option (in 2023 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status** Non Qualifying provision
£381m	£381m	£0.2m	

What is the problem under consideration? Why is government action or intervention necessary?

The Government has publicly committed to pursue legislative change to make better use of the skill mix in pharmacy teams to deliver more clinical services in the community and support wider NHS capacity. Reforming the legislation governing what requires 'supervision' by a pharmacist in a pharmacy is a key part of this.

Medicines legislation requires that the preparation, assembly, dispensing, sale and supply of pharmacy and prescription only medicines must be undertaken by, or under the supervision of, a pharmacist. As supervision is not defined in legislation, and there is relevant case law in this area, it is recognised that there is some disagreement as to what the law currently requires in terms of "supervision" – with much of the sector and profession concerned that case law means a pharmacist must directly supervise every individual transaction in the pharmacy.

Since the law was drafted, and case law came in, pharmacy technicians have become registered and regulated health professionals - capable of managing much of the technical dispensing process autonomously, without requiring supervision by a pharmacist. Reform will enable pharmacy technicians to take greater responsibility for running dispensaries, allowing pharmacists to spend a greater proportion of their time delivering patient-facing clinical services, using their training and expertise, including prescribing - to release capacity in the wider NHS.

What are the policy objectives of the action or intervention and the intended effects?

- enable both pharmacists and pharmacy technicians to operate at the top of their competence and make better use of the skill mix in pharmacy teams
- enable pharmacists to deliver more clinical services and supervise the operation of the pharmacy
- enable greater delegation of tasks to pharmacy technicians to deliver more autonomously as a registered professional within the pharmacy team
- create more fulfilling careers for pharmacy technicians, particularly in community pharmacy

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1 – Do Nothing

Option 2 (Preferred option) – Change legislation to enable pharmacists to authorise pharmacy technicians (and in specific and limited circumstances, other non-regulated members of the pharmacy team) to perform tasks that would otherwise need to be performed by or under the supervision of pharmacists – and for pharmacy technicians to take primary responsibility for the preparation and assembly of medicinal products in hospital aseptic facilities.

To inform this proposal we have conducted extensive pre-consultation with the sector, pharmacy regulators and professional bodies and the UKs four Chief Pharmaceutical Officers. We have also cleared the approach to changing the Medicines Act with the Office for Parliamentary Counsel. Throughout this consultation process we have iteratively developed proposals – more evidence for our recommended proposal is included in Evidence Base, where we also outline alternative options that we have considered and discounted.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 10/2028

Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** 0	**Non-traded:** 0	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Andrea Leadsom Date: 28/11/2023

Summary: Analysis & Evidence

Policy Option 1

Description: Business As Usual

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High: N/A**	**Best Estimate: 0**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	0		0	**0**
High	0		0	**0**
Best Estimate	0		0	**0**

Description and scale of key monetised costs by 'main affected groups'

The "business as usual" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero by definition.

Although set to zero for appraisal purposes, the status quo option maintains different interpretations of 'supervision', potentially inhibiting the use of the skill mix in the pharmacy team.

Other key non-monetised costs by 'main affected groups'

N/A

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	0		0	**0**
High	0		0	**0**
Best Estimate	0		0	**0**

Description and scale of key monetised benefits by 'main affected groups'

The "business as usual" option is the counterfactual scenario, against which other options are assessed. The value of costs and benefits are therefore zero by definition.

Other key non-monetised benefits by 'main affected groups'

N/A

Key assumptions/sensitivities/risks	Discount rate (%)
It is assumed that the current legislation would stay in place for the remainder of the appraisal period. Therefore, there is no change to cost or benefit under this option throughout the appraisal period.	

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0	**Benefits:** 0	**Net:** 0	N/A

Summary: Analysis & Evidence

Policy Option 2

Description: Change legislation to enable pharmacists to authorise others, in particular pharmacy technicians, to perform tasks that would otherwise need to be performed by or under the supervision of pharmacists – and for pharmacy technicians to take primary responsibility for the preparation and assembly of medicinal products in hospital aseptic facilities.

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	**PV Base Year** 2023	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: £124m	**High: £639m**	**Best Estimate: £**381m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	£3.1m	1	£0.2m	**£4.7m**
High	£3.1m	1	£0.2m	**£4.7m**
Best Estimate	£3.1m	1	£0.2m	**£4.7m**

Description and scale of key monetised costs by 'main affected groups'

The training costs are to be realised by the pharmacies choosing to utilise their pharmacy technicians to supervise the dispensing process (£2.1m).
There is a cost for pharmacists to take time to understand the change in regulations (£1.0m).
There is a cost for pharmacies to review and update pharmacy procedures and protocols to ensure safe and effective delivery of pharmaceutical services when dispensing is delegated to a pharmacy technician.

Other key non-monetised costs by 'main affected groups'

There may be impacts on safety, however this approach maintains that there must be a pharmacist responsible for every pharmacy premises and a registered pharmacy professional responsible for the dispensing of medicines, this is extremely low. A pharmacy technician is a registered and regulated healthcare professional in their own right, with education and training to undertake dispensing of medicines. We are also proposing a transition period before this legislation commences to allow regulatory rules and standards, and professional guidance to be issued to ensure good governance supports the implementation of this legislation in practice.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	N/A		£15.0m	**£128.7m**
High	N/A		£74.8m	**£643.4m**
Best Estimate	N/A		£44.9m	**£386.1m**

Description and scale of key monetised benefits by 'main affected groups'

Improved efficiency and cost effectiveness for pharmacy teams resulting from maximising the use of all professionals within pharmacy teams. Enable pharmacists to deliver more clinical services reducing time on tasks that can be safely delegated.

Other key non-monetised benefits by 'main affected groups'

Ensure the dispensing process is overseen by a suitably trained registered pharmacy professional and enable a better use of skill mix in pharmacy teams (improving pharmacist and pharmacy technician career prospects).
Improved patient satisfaction with the process of accessing medicines, due to reduced delays. Potential improvements to patient health resulting from more timely access to medicines.
Increased workforce available to fill vacancies in aseptic units.

Key assumptions/sensitivities/risks	**Discount rate**	3.5%

There is uncertainty around the proportion of time a pharmacist spends supervising the dispensing process, we assume a range of 10%-50%. We assume around 15 minutes is spent understanding the new regulation change.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m:**
Costs: £0.2m	**Benefits:** £44.9m	**Net:** £44.7m	N/A

Evidence Base

The problem under consideration and rationale for intervention

1. Medicines legislation requires that the preparation, assembly, dispensing, sale and supply of pharmacy and prescription only medicines must be undertaken by, or under the supervision of, a pharmacist. As supervision is not defined in legislation, and there is relevant case law in this area, it is recognised that there is some disagreement as to what the law currently requires in terms of "supervision" – with much of the sector and profession concerned that case law means a pharmacist must directly supervise every individual transaction in the pharmacy.

2. Since the law was drafted, and case law was established, pharmacy technicians have become registered and regulated health professionals - capable of managing much of the technical dispensing process autonomously, with reference to a pharmacist only where necessary. Reform will enable pharmacy technicians to take greater responsibility for running dispensaries, allowing pharmacists to spend a greater proportion of their time delivering patient-facing clinical services, using their training and expertise, including prescribing - to release capacity in the wider NHS.

3. Furthermore, the law currently allows 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. However, a pharmacist needs to be in a position to supervise a member of staff if they were to pass out the same medicine on a registered pharmacy premises. This has led to patients experiencing delays in receiving medicines when a pharmacist is absent from the pharmacy. Changing legislation is the only way to resolve this discrepancy and align bricks and mortar pharmacies with medicines delivery services and locker boxes.

4. Finally, the roles of pharmacists in hospitals are changing with more time spent in patient-facing clinical roles, this is expected to accelerate following the changes to pharmacist initial education and training that mean all newly qualified pharmacists will register as prescribers from 2026. This means pharmacy technicians are now often more experienced in aseptic production than some of their pharmacist colleagues – and yet in law, they must work under the supervision of a pharmacist. Changes to legislation would enable registered pharmacy technicians (in addition to pharmacists) to supervise aseptic units and allow optimal deployment of health care professionals.

5. Community pharmacies are private businesses who provide NHS pharmaceutical services as set-out in the Community Pharmacy Contractual Framework (CPCF) and equivalent frameworks in the Devolved Governments. Within the CPCF, and more recently within the Delivery plan for recovering access to primary care, the Government publicly committed to pursue legislative changes to make better use of the skill mix in pharmacy teams. Optimising and modernising 'supervision' legislation is a key element of this commitment.

Policy objective

6. This policy contributes to the ambitions of the NHS systems across all four nations of the UK, to further integrate community pharmacy into the NHS and maximise the use of skill mix in pharmacy teams, enabling them to meet more of the health needs of their local populations. Across other clinical settings, this proposal will enable registered pharmacy technicians to maximise the contribution they make within multi-professional teams.

7. Enabling pharmacy technicians to use their skills and knowledge to undertake more of the dispensing process may enable pharmacists to focus their clinical expertise and prescribing skills to support better patient outcomes. This may reduce the need for appointments in other parts of the Healthcare System, such as GPs and Urgent and Emergency care.

8. Over 1.3 billion prescription items are dispensed each year in community pharmacies as part of NHS primary care services in the UK. In addition to dispensing medicines, the range and volume of other services pharmacies offer has increased and is set to increase further. During the period of the 5-year deal the new clinical services which have been introduced are the Community Pharmacist Consultation Service, Discharge Medicines Service, Blood Pressure Checks Service, Smoking

Cessation Service, and Pharmacy Contraception Service (Annex A). For Pharmacists to offer this range of clinical services and to develop them further we need to enable pharmacists to spend less time on activities that can be safely delegated.

9. It is a government priority to strengthen the future NHS workforce and the skill mix in community pharmacy. NHS England have been prominent in the work to develop this proposal and extensive pre-consultation with the sector has been essential in its development.

Alternative options considered and discounted

10. To inform this proposal we have conducted extensive pre-consultation with the sector, pharmacy regulators and professional bodies and the UKs four Chief Pharmaceutical Officers. NHS England have also played a vital part in shaping how we make these changes. We have also cleared the approach to changing the Medicines Act with the Office for Parliamentary Counsel. Throughout this consultation process we have iteratively developed proposals and considered at great length what we should and should not include in legislation.

11. We considered being more enabling with changes, to allow a pharmacist to authorise any member of the pharmacy team. However, limiting “authorisation” to pharmacy technicians is a patient safety measure designed to ensure a registered pharmacy professional, who is accountable for their practice to the regulator, is going to be doing or supervising the preparation, assembly, dispensing and sale and supply of medicines.

12. We considered whether our policy aims could be achieved by issuing guidance. However, our legal advice is that issuing guidance alone would not be enough to achieve these proposals, the existence of case law meant legislative change was essential.

13. We considered and discounted the option of changing legislation to state that preparation, assembly, dispensing, sale and supply could be conducted by a pharmacist or pharmacy technician, or under the supervision of a pharmacist or pharmacy technician. Pharmacist training is five years at Master's level (national level seven) and pharmacy technician training is two years part-time, interspersed with work, at national level three. This means that pharmacy technicians can work autonomously but with reference to a pharmacist where necessary – our proposals reflect this. The exception to this is aseptic facilities, where the extensive post-registration training carried out by parts of the pharmacy technician workforce makes them equally as qualified as some pharmacists to supervise these facilities.

14. There are some activities reserved to a pharmacist that pharmacy technicians cannot undertake, for example, professional guidance states the clinical check must be conducted by a pharmacist. Furthermore, we are aware that the community pharmacy sector largely wanted the ability to authorise limited to the Responsible Pharmacist. We considered including restrictions such as this in legislation but determined that these decisions/restrictions are better set by the pharmacy regulators and professional bodies, who will support implementation of this legislation into practice. This prevents practice matters being set in inflexible ministerial legislation that is difficult to update as practice evolves.

15. Any one of three components of our proposal could be taken forward in isolation, however, this would be a missed opportunity to provide the more ambitious reform these proposals as a package will achieve.

16. We have considered splitting up the supervision of the dispensing process into preparation and assembly and sale and supply. The former is distinct from the stage of final supply to the patient or member of the public, and it could be argued that the preparation and assembly of medicines is more aligned with the education and training of pharmacy technicians. However, the recommended option (option 2) is highly enabling and leaves it to a pharmacist to decide on who is the most suitable person(s) to undertake the different stages of the preparation, assembly, dispensing, sale and supply of medicines. This approach is preferable than setting in legislation who must undertake which

activities, instead leaving it to pharmacists and professional regulation and guidance, which can adapt far more quickly to innovations in practice.

17. Enabling pharmacists to remotely supervise multiple retail pharmacy businesses was never considered an option. Policy to date, across the four nations, is that every pharmacy should have a pharmacist. This is not only to oversee and be legally responsible for the safe and effective delivery of pharmaceutical services, including the dispensing of medicine, but increasingly, to provide clinical services to patients, channel shifting work away from other parts of the NHS. The point of these proposals is to enable pharmacists to spend more time with patients, not less.

Description of options considered

Option 1 – Business as usual/no change

18. No regulatory changes are made. As a result, legal ambiguity around the interpretation of supervision continues and there are still legislative barriers to pharmacists delegating effectively to pharmacy technicians. This will continue to limit the impact of having a second registered and regulated pharmacy professional. Pharmacists would need to continue to supervise the dispensing process and so the time they could dedicate to delivering clinical services is limited. The skill mix of pharmacies are potentially not utilised to their full potential and the role of pharmacists is still not certain with regards to dispensing and sale of medicines. Pharmacy technicians would have to continue to work under the supervision of a pharmacist at hospital aseptic facilities, regardless of which professional had the most expertise to run the facility – this would maintain the issue aseptic facilities currently have recruiting someone suitably qualified to supervise the facility. This would impede ambitions across the UK for pharmacy to delivering more services and take pressure off other parts of the NHS.

Option 1 (Recommended) - Change legislation to enable pharmacists to authorise pharmacy technicians (and in specific and limited circumstances relating to checked and bagged medicines, other non-regulated members of the pharmacy team) to perform tasks that would otherwise need to be performed by or under the supervision of pharmacists – and for pharmacy technicians to take primary responsibility for the preparation and assembly of medicinal products in hospital aseptic facilities.

Proposal: Part 1 – Introducing authorisation of a pharmacy technician by a pharmacist

19. Currently section 10(1) of the Medicines Act 1968 and regulation 220 of the Human Medicines Regulations (HMRs) enables the preparation, assembly, dispensing, 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 with the authorisation of a pharmacist.

20. Under these proposals, subsection (1A) and section 10A will be inserted into the Medicines Act (1968) and regulation 220A will be added to the HMRs (2012). This will enable a pharmacist to authorise a registered pharmacy technician to either carry out tasks relating to the preparation, assembly, dispensing and sale or supply of medicines; or with the authorisation of the pharmacist, to supervise others to carrying out these tasks. Limiting these forms of “authorisation” to pharmacy technicians is a patient safety measure designed to ensure that the legislation starts from the premise that a registered pharmacy professional, who is accountable for their practice to the regulator, is going to be doing or supervising the preparation, assembly, dispensing and sale and supply of medicines.

21. Our proposal states that an authorisation given to a pharmacy technician can be expressed in either specific or general terms (e.g. relating to particular transactions or orders for medicines, or in general terms, potentially covering a range of prescriptions or categories of medicines). An authorisation can be given orally or in writing, may be subject to conditions or restrictions and may be varied or withdrawn by the pharmacist by whom it is given. In giving authorisation, a pharmacist must have due regard to patient safety and failure to comply with that requirement may lead to professional fitness to practice proceedings. This places an emphasis on professional regulation, rather than the criminal law.

22. This wording is intended to be enabling and sets a broad framework. 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, should they wish to do so (recognising this will mean those pharmacies forego the benefits of the changes). Government legislation will not set out practice matters (e.g. who is competent to perform specific tasks, using professional judgement to determine if a task is within their scope of practice, the keeping of records concerning an authorisation etc.). This allows for the pharmacy regulators to consult on and set out the detail in their rules/regulation/standards. Professional bodies can then support with associated guidance.

23. 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 possible.

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

24. Under these proposals, Regulation 220B will be inserted into the HMRs (2012), which will enable 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 pharmacists' absence (e.g. when the pharmacist is not interruptible in a consultation room or temporarily absent from the premises).

25. Authorisation under this proposal is intentionally broader than the authorisation under proposal 1, as any member of the pharmacy team can be authorised. The law currently allows 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, but a pharmacist needs to be in a position to supervise a member of staff if they were to pass out the same medicine on a registered pharmacy premises. This restriction has led to patients experiencing delays in receiving medicines when a pharmacist is absent from the pharmacy. Our proposal will bring arrangements in community pharmacies in line with arrangements for automated lockers, collection points and home deliveries.

26. In authorising these types of transaction, the pharmacist can specify any conditions or restrictions they deem appropriate. We would expect that pharmacy standard operating procedures and sale of medicines protocols would include clear instructions on the conditions under which a sale or supply should not go ahead, for example, if a patient presents with information that they have been prescribed a new medicine, report side-effects from taking their medicines, or has so called 'red-flag' symptoms which suggest more severe illness.

27. Again, as for proposal 1, practice matters will not be set out in government legislation (e.g. record keeping of authorisation), implementing this legislation in practice will require these to be set out by pharmacy regulators and professional bodies.

28. These proposals will apply to Great Britain and Northern Ireland.

Proposal 3 – supervision by pharmacy technicians at hospital aseptic facilities

29. Under these proposals, inserting regulation 4A in to the HMRs (2012) would permit registered pharmacy technicians to supervise the preparation, assembly and dispensing of medicines in hospital aseptic facilities. This would enable suitably qualified and experienced pharmacy technicians

to be responsible for a hospital aseptic facility without having to act under the supervision (or authorisation) of a pharmacist. To benefit from this provision, the pharmacy service must still be overseen by a chief pharmacist (or someone fulfilling the statutory functions of a chief pharmacist) who is responsible for the ensuring the safe and effective running of the pharmacy service.

30. Pharmacy technicians are increasingly the most experienced professionals working in aseptic units with many suitably qualified and experienced to oversee aseptic production. The roles of pharmacists in hospitals are changing with more time spent in patient-facing clinical roles, this is expected to accelerate following the changes to pharmacist initial education and training which mean all newly qualified pharmacists will register as prescribers from 2026. This means pharmacy technicians are now often more experienced in aseptic production than some of their pharmacist colleagues. We are proposing enabling pharmacy technicians, in addition to pharmacists, to be allowed to supervise aseptic preparation activity, allowing optimal deployment of healthcare professionals and service delivery for patients.

31. Robust governance arrangements will be required to ensure safe implementation of these proposals into practice. As for proposals 1 and 2, practice matters will not be set out into legislation, such as the level of experience or qualifications a pharmacy technicians must hold to fulfil these roles. These should be recognised for aseptic supervising and 'accountable' pharmacy technicians in Quality Assurance of Aseptic Preparation Services professional standards published by the Royal Pharmaceutical Society, and will be subject to separate consultation.

Background

Pharmacist and Pharmacy technician roles

What is Supervision?

32. Currently, medicines legislation requires that the sale and supply (regulation 220 of the Human Medicines Regulations 2012) and the preparation and assembly (section 10(1) of the Medicines Act 1968) of pharmacy[1] (P medicines) and prescription only medicines[2] (POM) must be undertaken by a pharmacist, or under the supervision of a pharmacist.

33. As supervision is not defined in legislation, and there is relevant case law in this area, it is recognised that there is some disagreement as to what the law currently requires in terms of "supervision". The explanation given in the consultation document provides an overview of the relevant legislation and case law to outline why practice has emerged as it has.

34. The proposed changes to legislation will not, in themselves, redefine "supervision" – and supervision by a pharmacist will continue as before, that is, a route to lawful preparation, assembly, dispensing and sale or supply of medicines. 'Authorisation' provides a new route to lawfully undertaking these activities, but supply by or under the supervision of a pharmacist will remain an option open to pharmacies, for example where a pharmacy does not employ a pharmacy technician.

The role of pharmacists

35. Section 72A of the 1968 Act provides that it is the duty of the responsible pharmacist to secure the safe and effective running of the pharmacy business regarding the retail sale and supply of medicinal products. Each retail pharmacy premises must have a RP on duty to lawfully operate. The proposals outlined in this consultation do not change this fact. The RP may only be responsible for one premises (which includes any associated premises), at any one time, and the pharmacy regulators

[1] Pharmacy (P) - an intermediate level of control, can be bought only from pharmacies and under a pharmacist's supervision

[2] Prescription-Only Medicine (POM) - has to be prescribed by a doctor or other authorised health professional and it has to be dispensed from a pharmacy or from another specifically licensed place

have a power to introduce an exception to this rule. No provisions have been introduced to date to allow an exception.

36. The Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008, is the key piece of legislation that details the responsibilities of the responsible pharmacist. The Regulations provide that the responsible pharmacist may only be absent for up to two hours during pharmacy business hours (within a 24 hour period).

37. The retail sale and supply of medicinal products on a general sale list may still take place from the premises during the period of absence of the responsible pharmacist. However, the Human Medicines Regulations 2012 (Regulation 220) provides the retail sale and supply of prescription only medicines (POM) and Pharmacy medicines (P medicines) may only lawfully take place if a person is lawfully conducting a retail pharmacy business, and the product is sold, supplied, or offered for sale or supply on premises that are a registered pharmacy, and the transaction is carried out under the supervision of a pharmacist.

Professional regulation of pharmacists

38. The term 'Pharmacist' is a protected title by law. All pharmacists, whether working in the NHS, private or voluntary sectors in England, Wales, and Scotland, must be registered with the General Pharmaceutical Council (GPhC), or the Pharmaceutical Society of Northern Ireland (PSNI) - the statutory regulators for pharmacy professionals in Great Britain and Northern Ireland. Pharmacists are a registered profession in the United Kingdom and undertake 4 years' undergraduate training – accredited by the pharmacy regulators - followed by 1 year pre-registration training and registration exam. Registered pharmacists must also undertake annual revalidation to make sure they remain fit to practise through using, maintaining and developing their professional knowledge, attitudes and behaviours.

39. There are currently 64,267[3] pharmacists registered in Great Britain across all settings and 2,810[4] in Northern Ireland.

The role of pharmacy technicians

40. Pharmacy technician's main role is to undertake the procurement, storage, assembly, preparation, sale, supply, administration and education of medicines and medicinal products. Pharmacy technicians work as part of multidisciplinary teams across a range of settings. Pharmacy technicians are patient facing and provide medicines optimisation services with clinical setting exposure from pre-registration training. These settings include:

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

Professional regulation of pharmacy technicians

41. The term 'Pharmacy Technician' is a protected title by law. All pharmacy technicians, whether working in the NHS, private or voluntary sectors in England, Wales, and Scotland, must be registered with the General Pharmaceutical Council (GPhC), the statutory regulator for pharmacy professionals in Great Britain. As of 30 September 2023, there were 25,696[5] pharmacy technicians registered in Great Britain across all settings.

[3] The GPhC Register as of 30 September 2023 – Trend Date - GPhC registers data | General Pharmaceutical Council (pharmacyregulation.org)

[4] The PSNI Register as of 31 May 2022 – PSNI Annual Report and Accounts 21/22 - Annual-Report-and-Accounts-2021-22.pdf (psni.org.uk)

[5] The GPhC Register as of 30 September 2023 – Trend Date - GPhC registers data | General Pharmaceutical Council (pharmacyregulation.org)

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

Pharmacy technician education and training requirements

43. Pre-registration trainee pharmacy technicians undertake a two-year training programme and must achieve GPhC approved education that meets the 2017 Initial Education and Training Standards. The underpinning curricula, as a minimum, includes: chemistry, microbiology, physiology, action and uses of medicines, law, pharmaceutics, dispensing, pharmacy production, professional practice, ethical decision making, medicines optimisation and accuracy checking.

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

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

46. Similarly, to registered pharmacists, registered pharmacy technicians in GB must undertake annual revalidation to make sure they remain fit to practise through using, maintaining and developing their professional knowledge, attitudes and behaviours.

Safety

47. The law places a statutory duty on the Responsible Pharmacist and Superintendent Pharmacist to 'secure the safe and effective running' of a retail pharmacy business with regard to the sale and supply of medicines. Similarly, a Chief Pharmacist has a statutory for securing that the pharmacy service for which they are responsible is carried on safely and effectively.

48. To maintain public safety and provide assurance to the people that use pharmaceutical services, it is important that a qualified and regulated pharmacy professional be involved in the dispensing of Prescription only medicines (POM) and Pharmacy (P) medicines at all times. The education and training and continued professional development of registered pharmacy professionals makes them uniquely qualified to manage the preparation and dispensing of medicines and advise patients about medicines, including how to take them, what reactions may occur and answer patients' questions.

49. The proposed changes to legislation are intended to be enabling and set a broad framework. 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 should they wish to do so (recognising this will mean those pharmacies forego the benefits of the changes). Government legislation will not set out practice matters (e.g. who is competent to perform specific tasks, the keeping of records concerning an authorisation etc.), but is unpinned by robust governance systems. This allows for the pharmacy regulators to consult on and set out the detail in their rules/regulation/standards. Professional bodies can then support with associated guidance to ensure any changes to practice are in-line with what is considered best practice in the profession and to maintain safe and effective pharmaceutical services.

Aseptic facilities

50. Aseptically produced injectable medicines have an annual cost of £5 billion representing 80% of the total annual medicines expenditure in NHS hospitals in England alone. The majority are intravenous chemotherapy, parenteral nutrition and antibiotics in ready-to-administer form, made by NHS or licensed commercial aseptic manufacturing facilities. As these products are infused directly into patients, their production must be of the highest possible standard. They are made in highly regulated, specialist units and have limited shelf-life, making them less suitable for traditional manufacture and/or importation. The use of these medicines has been increasing and advances in medical science and therapies suggest this sector will grow substantially in the next decade. NHS facilities are run mostly by hospital pharmacies and the majority do not hold an MHRA authorisation to manufacture medicines, but prepare medicines under the Section 10 exemption in the Medicines Act 1968.

51. Current law requires such units to be run by a registered pharmacist, but in practice a pharmacy technician is often responsible for the day to day running of the unit.

Evaluation of costs and benefits

52. The remainder of this IA examines the potential costs and benefits of the proposed regulatory change. This impact assessment appraises over a ten-year period from April 2024.

Benefits

Release pharmacists time – Reduced labour cost

53. Adjustments to supervision legislation which enables supervision by a pharmacy technician with the authorisation of a pharmacist will potentially lead to labour cost savings. Below we estimate the savings expected from the task of supervision now being completed with lower cost staff members.

54. To understand the wage difference between pharmacy staff, data from the Annual Survey of Hours and Earnings (plus an additional 30% for non-wage costs such as National Insurance and pensions contributions) is used. Table 1 shows that a pharmacy technician costs £18.50 per hour compared to a pharmacist at £30.63 per hour. A pharmacy technician is therefore assumed to cost 40% less than a pharmacist.

Table 1: Differential in wage rates, using salary information from ASHE provisional 2022[6]

Occupation (4 digit SOC)	**Hourly Cost**[7]	**On-costs uplift**	**Hourly Cost including on-costs**
Pharmacist (2251)	£23.56	30%	£30.63
Pharmacy Technician (3212)	£14.23	30%	£18.50

55. To estimate how much pharmacist time is saved per item Table 2 breaks down the tasks associated with dispensing an item and the relevant staff member supervising the dispensing.

56. Dispensing covers several processes such as the receipt of a prescription, clinical and accuracy checks, preparation, assembly and supply of medicines and liaising with the patient to ensure they know how and when to take the medicine. The table below outlines the main dispensing tasks that will be impacted by these changes, setting out the estimated time taken for each so that the time

[6] Earnings and hours worked, occupation by four-digit SOC: ASHE Table 14.5a - Office for National Statistics (ons.gov.uk)

[7] Hourly rate taken as the higher of the mean and median. This uses data released in October 2022, so may not take full account of more recent inflationary effects on wages.

savings can be assessed:

Table 2: Supervision requirements for dispensing tasks

		Supervision required for task	
Dispensing Task	**Average direct staff time per item**	**Option 1 – BAU**	**Option 2**
Clinical Check	1 minute	N/A -Task conducted by Pharmacist	N/A - Task conducted by Pharmacist
Pick and label medicine, accuracy check and hand to patient	4 minutes	By Pharmacist	By Pharmacist Technician
Total	5 minutes		

57. Next, estimates of how much pharmacist time is saved per item is calculated. From the table above it shows four out of the five minutes of direct staff time is currently supervised by a pharmacist and could be supervised by a pharmacy technician. Under option 2, a pharmacist may still supervise anyway.
58. The intensity of supervision is likely to be dependent on several factors and we do not know the ratio of supervision time to direct staff time. For example, some pharmacists might directly observe prescriptions being prepared for every patient, or some may feel that clinical checks and an awareness of what is being dispensed by other suitably qualified members of the pharmacy team is enough. We assume, around 10%-50% of the direct staff time as supervision time.
59. As shown in Table 2 the regulation amendments will still require Pharmacists to continue to conduct a clinical assessment of every prescription (clinical check), to determine the suitability of the medication, the appropriateness of the quantity and its dose frequency for the patient.
60. Table 3 outlines the volumes of prescription items dispensed by country and financial year. Northern Irelands available data on dispensing volumes is in calendar years which is assumed to be financial years to remain consistent with the other countries available data and won't impact estimates given the stability of the volumes. Overall, across the UK around 1.28bn items are dispensed each year.

Table 3: Prescription items dispensed in the UK by financial year

(m)	**2018/19**	**2019/20**	**2020/21**	**2021/22**
England	**1,014**	**1,035**	**1,016**	**1,042**
Scotland[8]	**104**	**107**	**103**	**107**
Wales[9]	**80**	**82**	**81**	**83**
Northern Ireland[10]	**42**	**43**	**42**	**43**
Total	**1,240**	**1,267**	**1,242**	**1,275**

61. Due to the level of uncertainty in dispensing volumes which have fluctuated annually, we assume 2021/22 volumes are held constant over the 10-year appraisal period. This is likely a conservative assumption for the estimation of benefits as it is possible that there is items growth. We do not

[8] Prescribed and Dispensed - Prescribed & Dispensed 2022 - Scottish Health and Social Care Open Data (nhs.scot)

[9] Prescriptions in Wales: interactive dashboard | GOV.WALES

[10] Prescription Cost Analysis for Northern Ireland, 2022 - GOV.UK (www.gov.uk)
Prescription Cost Analysis (hscni.net)

expect the proposals to impact on dispensing volumes or supply chains, just the staff mix that does the dispensing.

62. Not all pharmacies will have pharmacy technicians which they can utilise once the changes in regulations are made, and the England HEE workforce survey 2022[11] shows that there are fewer pharmacy technicians than pharmacists. Specifically, the survey found there were 5,252 pharmacy technicians (FTE) compared to17,843 pharmacists in England. This suggests that up to 29% of pharmacists could have some of their time replaced by pharmacy technician time.

63. As a sense check, on 30th September 2023, there were 64,267 registered pharmacists and 25,696 registered pharmacy technicians in England, Scotland and Wales (headcount)[12]. This suggests a ratio could be that up to around 40% of pharmacists could have some of their time replaced by pharmacy technician time.

64. There is no information on the extent of different interpretations of the current regulations in practice. Removing ambiguity in legislation could also serve to protect pharmacists who may already be practising in a way we consider aligned with our aspirations but could fall foul of the interpretation in case law. We assume that 50% of pharmacies (and therefore 50% of items dispensed) are already interpreting the legislation in the ways outlined in option 2. Given the uncertainty of this assumption this is explored further in the sensitivity analysis section, with a range of assumptions on current supervision practises.

65. Taking the assumed ranges of supervision time and multiplying by total items dispensed suggests total supervision hours of 8.5m-42.5m hours. Due to workforce numbers a maximum of 29% or 2.5m-12.3m hours could be covered by a pharmacy technician. The difference between the costs of a pharmacist and pharmacy technician is £12.13/hour, so this time is valued at £30m-£150m. However, if 50% of pharmacies are already practising in line with proposal then the valuation drops to £15m-£75m:

Table 4: Annual Benefits

	Option 2	
Supervision % of direct staff time	10%	50%
Pharmacist Supervision Time (4 mins x total items) Counterfactual Hours	8.5m	42.5m
Proportion of supervision time delegated	29% delegated to PT	
Delegated Supervision Hours	2.5m	12.3m
Cost saving per hour	£12.13	
Maximum annual savings	£30m	£150m
Assumed % already practising in line with Option	50%	
Annual savings	£15m	£75m

66. We find that each year these suggested regulation changes could save pharmacies around £15m - £75m in labour costs. These savings are representative of the time saved for pharmacists who can now use that time differently. Legislation will continue to require a RP to be in charge of the business at the premises. The savings are therefore unlikely to be cash releasing as pharmacies will still have the same number of employees. However, in the longer term these savings outlined should allow pharmacists to provide more services as outlined in the next section.

67. This analysis also only focuses on the dispensing of prescription medicines, an NHS pharmaceutical service and not sale of pharmacy (P) medicines. There is no data available on pharmacy (P) volumes, so we are unable to quantify the potential benefits of a change in supervision for the sale of

[11] Community Pharmacy Workforce Survey | Health Education England (hee.nhs.uk)

[12] GPhC registers data | General Pharmaceutical Council (pharmacyregulation.org). Headcount based.

these within the impact assessment. However, although the proportion of NHS income varies between different community pharmacies, NHS income and therefore dispensing of prescription medicines tends to make up the majority of income (figures quoted of 80%-90%), particularly for smaller independent pharmacies.

Release pharmacists time – enable provision of more services

68. These options free up pharmacists' time to deliver more clinical services, but still be readily available to communicate with patients or the wider pharmacy team. For example, in the above calculations pharmacists may be now able to perform more services with the 24-120 seconds per item dispensed saved from no longer needing to supervise. Table 5 shows the number of community pharmacies per country. If the total pharmacies are divided by the 2021/22 dispensing volumes, we find an average of around 2,000 items dispensed per pharmacy per week. This suggests 1-4 hours (accounting for current understanding of supervision and pharmacies that may not have a PT) of pharmacist time could be freed up by an average pharmacy each week.

69. We only consider the benefits of these additional services that go above and beyond that of the labour costs we have monetised. Although unmonetised it is likely this impact will be small given the quantified savings already outlined.

Table 5: The number of community pharmacies in the UK at March 2022

	Pharmacies
England[13]	11,121
Scotland[14]	1,354
Wales[15]	712
Northern Ireland [16]	526
Total (UK)	13,713

70. The benefits of this change will be to pharmacies that are able to deliver supervision using less costly staff but still receive the same fees for their dispensing service. Although these savings may not be cash releasing, we anticipate that it will free up pharmacy time which can be used to focus on providing a wider range of services for patients than can be done under the current requirements, while continuing to provide the current services.

71. By allowing pharmacists to no longer be aware, or substantively aware of the individual transactions, could free up time for them to focus on providing a wider range of services for patients than can be done under the present regulations, while continuing to provide patients with the medicines they need.

72. This increase in clinical service provision may deliver benefits to both the NHS and community pharmacies as set out below. However, these benefits rely on the relative gains of what the pharmacist will be doing against what the pharmacy technician will no longer be doing.

    a. Increased clinical service provision could result in health improvements for patients. For example, if the pharmacist has more capacity to spend time with patients and provide advice on healthy living and selfcare, as well as delivering valued clinical services such as vaccinations, blood pressure monitoring and medication advice.

    b. The increased capacity to see patients within pharmacies may also help reduce pressure on other parts of the NHS. For example, the Community Pharmacy Consultation Service is designed to allow pharmacies to take referrals for minor illnesses from NHS 111, GP surgeries, and urgent and emergency care settings. Previous impact assessments

[13] Pharmacy Openings and Closures - PHARMACY_OPENCLOSE_202304 - Open Data Portal BETA (nhsbsa.net)

[14] Dispenser Location Contact Details - Datasets - Scottish Health and Social Care Open Data (nhs.scot)

[15] Community pharmacy services: April 2021 to March 2022 | GOV.WALES

[16] General Pharmaceutical Services Annual Publication 2021/22 (hscni.net)

considering the expansion of this service within the Community Pharmacy Contractual Framework has highlighted the potential for this service to significantly reduce the number of GP appointments and A&E visits required. A 2015 survey of GPs estimated that approximately 2% of GP appointments could have been dealt with by community pharmacy instead[17], whilst the PSNC community pharmacy advice audit[18] found that almost half of patients who had an informal consultation in a pharmacy, would have visited their GP had they been unable to contact their community pharmacy.

c. Pharmacies who offer additional clinical services can increase their income. For example, private clinical services could include the provision of private seasonal flu jabs, travel vaccinations, or test and treat services, whilst NHS services could include taking referrals from the Community Pharmacy Consultation Service (£14 per consultation), the New Medicines Service (approx. £24 per consultation) or the Blood Pressure Checks Service (£15 for a clinic check and £45 for ambulatory blood pressure monitoring).

73. However, it is difficult to further quantify these benefits as it is not known what mix of additional clinical services might be offered by pharmacists. It is also important to note that, where NHS clinical services are funded from the Community Pharmacy Contractual Framework, under the terms of the 5-year deal, the total funding envelope is currently fixed until the end of the 2023/24 financial year at £2.592bn. This flat cash funding deal will naturally constrain the amount of additional income that pharmacies can make from NHS services, at least in the short term. This is particularly relevant as the benefits rely on the relative gains of what the pharmacist is freed up to do in comparison to what the pharmacy technician will no longer be doing.

Skills mix and creating engaging roles

74. Making this regulatory change will ensure pharmacy professionals work to the top of their competence, which is an aim the government is pursuing in a range of health care areas. A number of research studies[19] have identified a lack of distinction between the tasks undertaken by dispensing assistants and pharmacy technicians in community pharmacy. In addition, pharmacy technician roles in community pharmacy are currently limited compared to equivalents in secondary care. This proposal will enable pharmacy technicians to take greater responsibility for running dispensaries. Pharmacists will also be enabled to spend a greater proportion of their time delivering patient-facing clinical services, using their training and expertise, including prescribing.

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75. Currently pharmacies are finding it difficult to fill pharmacy technician roles. From the 2022 England Community Pharmacy Workforce Survey respondents were asked to rate roles in terms of how easy or difficult it was to fill vacancies. Although there is regional variance in reported difficulties of filling vacancies found within the survey, overall around 60% of respondents found the pharmacy technician role 'fairly' or 'very' difficult to fill compared to 3% suggesting the pharmacy technician role was 'fairly' or 'very' easy to fill. For all roles there was an increase in the vacancy rate, but pharmacy technicians had the highest rate at 20%.

76. A reason for the difficulty recruiting is suggested by the Community Pharmacy Workforce Development Group (CPWDG). At present, formal Continued Professional Development for pharmacy colleagues in the community sector is limited, and uptake is variable. This has acted as a barrier to career progression, compounding issues with job satisfaction and retention. Additionally, the CPWDG recommends pharmacy teams should be supported to take on additional tasks, which allow pharmacists to deliver further clinical services.[20]

77. These regulatory options will therefore improve pharmacy career development alongside the consultation to add Pharmacy Technicians to the list of registered health professionals able to supply and/or administer medicines under Patient Group Directives (PGDs). We have not quantified the

[17] Primary Care Foundation, Making Time In General Practice, October 2015. https://thehealthcreationalliance.org/wp-content/uploads/2018/11/Making-Time-in-General-Practice-FULL-REPORT-06-10-15.pdf

[18] Pharmaceutical Services Negotiating Committee, Pharmacy Advice Audit 2022. https://psnc.org.uk/wp-content/uploads/2022/06/PSNC-Pharmacy-Advice-Audit-2022-Full-Report.pdf

[19] http://pharmacyresearchuk.org/wp-content/uploads/2016/05/Pharmacy_Research_UK_Report_FINAL_-_Post-review_clean.pdf

[20] cpwdg-report-a-review-of-the-community-pharmacy-workforce-final.pdf (wordpress.com)

potential impact of the regulation changes on PT recruitment and growth of the profession in community pharmacy.

Consistency and convenience

78. Clarifying the meaning of supervision will ensure consistency of practise across pharmacies. The legislation change will remove the ambiguity of the term supervision and ensure pharmacies fully understand the regulations.

79. Furthermore, the law currently allows 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. However, a pharmacist needs to be in a position to supervise a member of staff if they were to pass out the same medicine on a registered pharmacy premises. Clarifying legislation to allow the handing out of suitably checked medicines in the absence of a pharmacist would align bricks and mortar pharmacies with medicines delivery services and locker boxes.

80. Additionally, it will likely lead to an improvement in the quality of service, as patients will no longer experience delays in receiving medicines when a pharmacist is absent from the pharmacy or repeat visits to collect prescriptions. Data from Department for Transport costs of travel[21], combined with an average distance from a pharmacy of 20 minutes walking time[22], suggests that an average £2.10 travel cost to visit a pharmacy. This would be the cost to a patient arriving at a pharmacy to find they were unable to collect their medicine.

Increased workforce available to fill vacancies in aseptic units.

81. For aseptic facilities, extensive post-registration training carried out by parts of the pharmacy technician workforce makes them equally as qualified as some pharmacists to supervise these facilities. This means some pharmacy technicians are now often more experienced in aseptic production than some of their pharmacist colleagues. Pharmacy technicians currently have to work under the supervision of a pharmacist at hospital aseptic facilities, regardless of which professional had the most expertise to run the facility. This is leading to aseptic facilities currently facing issues recruiting someone suitably qualified to supervise the facility.

82. Legislation change would enable registered pharmacy technicians in addition to pharmacists to supervise aseptic units and allow optimal deployment of health professionals. This should help to fill vacancies in aseptic units and maximise the possibility of producing injectable medicines; a sector where advances in medical science suggest this sector will grow substantially, and therefore maximise the health benefits to patients.

83. We do not have access to the number of aseptic units, the staffing levels within the units, or vanacny rates. Therefore we are unable to quantify the benefits of this proposal.

Summary of Benefits

84. The benefits from these regulation changes are outlined in the table below:

Table 6: Summary of Benefits

Group affected	Impact	Present value, £m - Option 2
Monetised benefits		
Contractors	Release pharmacist time (net of lost pharmacy technician time) - labour savings	£15m - £75m

[21] DfT on valuing walking times can be found in table A1.3.1 of their data book https://www.gov.uk/government/publications/tag-data-book. £6.71 is the perceived cost of non-working time per hour in 2023 prices.

[22] DHSC commissioned analysis in March 2021 on the walking distance between every postcode in England and the closest 5 pharmacies. Which showed a population weighted average of 1 mile. We assume 1 mile is equivalent to 20 minutes walking time.

Non-monetised benefits		
Contractors	Release pharmacist time - enable provision of more services	Unmonetised but expected to increase income of pharmacies
	Skills mix and improve pharmacy career prospects	Unmonetised but expected to improve skills mix and career prospects
	Consistency and convenience	Unmonetised but expected to create consistent practise across pharmacies
Aseptic Units	Increased workforce and filling of vacancies	Unmonetised but expected to aid workforce shortages
Patients	Release pharmacist time - enable provision of more services	Unmonetised but expected to increase amount of time pharmacists spend with patients and health benefits of clinical services
	Consistency and convenience	Unmonetised but expected to make a more convenient experience for patients

85. The benefits will be predominately based around pharmacists having more time to complete clinical services and interact with patients as well as the benefits from giving more responsibility to pharmacy technicians.

Costs

Reduced activity from Pharmacy Technicians

86. This regulation change will enable pharmacy technicians to supervise the dispensing process. The benefits of the pharmacist getting more time available has been set out. Conversely, the time given up by the pharmacy technician to now do the supervision the pharmacist was doing before should be considered. The estimated 24-120 seconds per item dispensed, or 1-4 hours by an average pharmacy per week potentially saved in pharmacist time would theoretically be matched by lost pharmacy technician time.

    We have assumed that in calculating the costs and benefits that the time a pharmacist gains from less supervision and the time a pharmacy technician loses from increase supervision is balanced out, with the monetised difference being the higher value of the pharmacist's time. It is likely that the pharmacy technician will continue to do the same technical work they normally do around the extra supervision
    activity.

Impact on wages from increased responsibility for PT's

87. Through the increase in responsibility of PT's this may increase wages as a result, giving them greater bargaining power.

Training costs

88. For pharmacies to fully realise the benefits of the adjustment in the regulation there would likely be training costs involved. Pharmacy technicians will potentially need to be upskilled to supervise.

89. We estimate this training will cost £500 which is of a similar quantum to set up fees provided for other clinical services[23] introduced over recent years. This will cover the costs of supervision training as well as the training of the entire team to understand new roles and responsibilities. £500 equates to around 27 hours of pharmacy technician time.

90. To understand the cost of training Table 7 shows the data available for the UK. Note this is not based on the same year and instead uses the most recent information, which is from 2019 to 2022.

Table 7: Community pharmacy workforce in the UK, Headcount (FTE)

Headcount (FTE)	Pharmacists	Pharmacy Technicians

[23] CPCS: £600-£900, DMS:£400, BP Checks: £440, SCS: £1,000, PCS: £900

England (2022)[24]	27,711 (17,843)	6,544 (5,252)
Scotland (2022)[25]	1,819 (1,368)	1,004 (784)
Wales (2019)[26]	1,084 (806)	811 (651)
Northern Ireland (2020)[27]	1,522 (900)	N/A
Total (UK)	32,136 (20,917)	8,359 (6,687)

91. Additionally, as assumed previously, there is a range of interpretations of supervision at present due to the ambiguity of the definition of supervision. Therefore, the training cost estimates follow the same assumption that 50% of the pharmacies already interpret the legislation as proposed. This accounts for some pharmacies already having trained their staff.

92. If we take this information from the pharmacy workforce surveys on the current number of pharmacy technicians (headcount) we estimate this will cost around £2m in total. We then assume an ongoing cost per year of £0.2m if around 10% of pharmacy technicians join the workforce each year. This assumption is highly uncertain given unavailability of data. Data shows the number of PT's has reduced from 2017 to 2022 (Headcount from 7,901 to 6,544), so this assumption primarily accounts for labour turnover each year. Although we have not quantified the potential impact of the regulation changes on PT recruitment this assumption should quantify the training cost impact of this.

Table 8: Training costs for pharmacies in the UK

Country	Option 2	
	Initial trainings costs	Annual training cost
England	£1.6m	£164,000
Scotland	£0.25m	£25,000
Wales	£0.20m	£20,000
Northern Ireland	Not a registered profession	
Total (UK)	£2.1m	£209,000

93. However, the legislation is enabling so it will be at the discretion of the pharmacy to implement the change. If the pharmacy finds the cost of the training too high for the benefit of reduced pharmacist time spent supervising dispensing, then there is no obligation to provide this training.

Time spent understanding regulation changes

94. The adjustment to the regulations will need to be read and understood by the pharmacy staff. To estimate the impact of this it is assumed that it will take an hour of pharmacist time to understand and communicate the regulation change.

95. Using the information in Table 7 it shows there are around 32,000 pharmacists. The estimated cost of an hour per pharmacist is just under £1m.

Table 9: Estimated cost to understand regulation change

Number of pharmacists	32,136
Hourly cost	£30.63
Time spent	1 hour
Cost	£984,000

Safety - Risk of inappropriate supply of medicines

[24] Community Pharmacy Workforce Survey | Health Education England (hee.nhs.uk)

[25] https://turasdata.nes.nhs.scot/data-and-reports/other-workforce-statistics/pharmacy-workforce/?pageid=6207

[26] https://heiw.nhs.wales/files/pharmacy-report-final/

[27] doh-pharmacy-workforce-review.pdf (health-ni.gov.uk)

96. An aim of these regulation changes is to recognise the role of procedures and system governance in promoting/maintaining patient safety. Overall, we find option 2's regulation changes pose no additional risks.

97. The National Reporting and Learning System (NRLS) is a largely voluntary scheme for reporting patient safety incidents. Data for 2021-22 shows that 1,921 incidents were reported in community pharmacy. The majority of these related to medication and for 96% of incidents the reported degree of harm was no harm.

Table 10: Reported incidents by degree of harm[28], by care setting, England: Apr 2021 - Mar 2022[29]

Community Pharmacy	No Harm	Low	Moderate	Severe	Death	Total
Number of Incidents	1,752	139	30	0	0	1,921
Percent	91	7	2	-	-	100

98. The latest NPA quarterly medication safety update showed that the main contributing factors to patient safety incidents were work and environment factors (41% of incidents) which includes time pressures, understaffing and poorly organised working environments, as well as Look Alike Sound Alike factors (23% of incidents) such as similar name, similar packaging etc.

99. A minimum of two people should be involved in the dispensing process. Ideally, the person undertaking the accuracy check should not be involved in the assembly process, to reduce the potential risk to patient safety and likelihood of errors.

100. Pharmacists will continue to conduct a clinical assessment of every prescription, to determine the suitability of the medication, the appropriateness of the quantity and its dose frequency for the patient. Pharmacists therefore will still have a key role in patient safety by ensuring that medicines are prescribed safely. The clinical check of prescribed medicines prior to dispensing is a crucial 'safety net' in preventing patient harm.

101. There should be no additional risks incurred from this change in practice from option 2 on patients as the pharmacy technicians will have the necessary training or competence to ensure safe and effective pharmaceutical services. Additionally, training will be required to supervise the dispensing process reducing any risk from a change in practise.

102. Robust governance arrangements will be required to ensure safe implementation of these proposals into practice. These should be recognised for aseptic supervising and 'accountable' pharmacy technicians in Quality Assurance of Aseptic Preparation Services professional standards published by the Royal Pharmaceutical Society, and will be subject to separate consultation.

Summary of Costs

Table 11: Summary of Costs

Group affected	**Impact**	**Present value, £m – Option 2**
Monetised costs		
Contractors	Training costs	£2.1m (£209k ongoing)
	Understanding regulations	£984k

[28] **no harm** – a situation where no harm occurred: either a prevented patient safety incident or a no harm incident; **low harm** – any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons; m**oderate harm** – any unexpected or unintended incident that resulted in further treatment, possible surgical intervention, cancelling of treatment or transfer to another area, and which caused short-term harm to one or more persons; **severe harm** – any unexpected or unintended incident that caused permanent or long-term harm to one or more persons; **death** – any unexpected or unintended event that caused the death of one or more persons.

[29] NHS England » National patient safety incident reports up to June 2022

Non-monetised costs		
Contractors	Reduced activity from Pharmacy Technicians	Unmonetised but not expected to decrease income of pharmacy
	Impact on wages from increased PT responsibility	Unmonetised but expected to have little impact on wages
Patients	Safety	Unmonetised but expected to have little or no impact on safety

Summary of all costs and benefits

103. This section aggregates the quantified costs and benefits. The main quantified costs are associated with the training and understanding regulations. The benefits are the released pharmacist time.

104. These results are summarised in Table 12 below. The present value of these benefits over the ten-year period is £386 million for option 2. The present value of the costs is £4.7 million, leading to an overall net present value (NPV) of £381 million.

Table 12: Aggregate quantified impacts of proposed policy

Option 2:

(£m)	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7	Yr 8	Yr 9	Yr 10	NPV
Understanding Regulations	1.0										1
Training Costs	2.1	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2	3.7
Released Pharmacist Time	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	44.9	386.1
Net Benefit	41.8	44.6	44.6	44.6	44.6	44.6	44.6	44.6	44.6	44.6	381.4

Risks and Sensitivities

Intensity of Supervision Assumption

105. Information on supervision is limited so assumptions have been made around the time taken to supervise each item dispensed and therefore the amount of time that could potentially be replaced by pharmacy technician time. Below we outline a range of scenarios and the impact on the estimates.

106. To conduct the sensitivity analysis, we take a range of proportions of supervision to direct staff time: 1%, 5%, 7.5%, 60%, 70% and 80%.

107. Table 13 shows the impact on the differing proportions of time to supervise with the IA's central assumptions highlighted in bold (10%-50%). It shows that a lower estimate of 5% would still cover the costs incurred from training and understanding legislation under option 2.

Table 13: Sensitivity analysis, range of supervision assumptions and estimated savings

Supervision as a % of direct staff dispensing time	Annual Pharmacist time released
1%	£1m

5%	£7m
7.5%	£11m
10%	**£15m**
50%	**£75m**
60%	£90m
70%	£105m
80%	£120m

108. This assumption of the intensity of supervision has a linear impact on the final estimates for the labour costs savings. Given the uncertainty and unavailability of data, the benefits realisation uses a large range from 10%-50%.

109. To note there may be other fixed costs not factored into this impact assessment that could prevent pharmacies from taking full advantage of the benefits of this legislation change. Stakeholders are invited to send over evidence of these issues as part of the consultation.

Pharmacist to PT ratio and the proportion of pharmacies already operating in line with proposals sensitivity analysis

110. As with the intensity of supervision assumption all assumptions have a linear impact on the savings due to the calculation being a product of the assumptions, wage differences, items dispensed and items dispensing time. Therefore, below we outline assumptions that will result in a 0 NPV. However it is important to note that non-monetised costs would likely result in an overall cost if the benefits were equal to the monetised costs. This sensitivity analysis will however show the impact of changes in the assumptions.

Take up of the legislation

111. This is not explored within the IA, but we explore this impact on the benefits realisation. As with the intensity of supervision assumption this has a linear impact on the estimated savings from the options as shown below.

Monte Carlo Analysis – Option 2

112. The monetised benefits outlined for labour cost savings include a range of uncertain assumptions. We therefore conduct a Monte Carlo analysis to understand how adjustments to the assumptions in the analysis could impact the outputs.

113. Monte Carlo analysis is used to help quantify the impact of risk and uncertainty. It involves repeated random sampling to obtain a range of results which can aid in the understanding of the distribution of expected outputs. In this case we run a sample of 100,000 potential scenarios altering four assumptions:

Option 2	Minimum	Maximum
Supervision Intensity	10%	50%
Pharmacist to PT ratio	29%	40%
Already practicing option	25%	75%
Uptake of regulatory change	0%	100%

114. The ranges set for supervision intensity follow the range found in the main analysis. The pharmacist to PT ratio is based on the two outlined scenarios in the IA. Given the large amount of uncertainty of the number of pharmacies already operating in line with the proposal, we take 25% either side of our main assumption. Finally, we add in an assumption around the actual uptake of the regulatory change. However, it is important to note that although this can potentially significantly reduce the expected savings, costs would fall in equal measure.

115. The analysis takes a random percentage from between or at the minimum and maximum for each of the parameters outlined and then calculates the expected labour cost saving as outlined in the main analysis section. For example, we may have a scenario where supervision intensity is 22%, pharmacist to PT ratio is 40% and those already practicing the option being 47%. This is then repeated 100k times to give us a range and average expected saving.

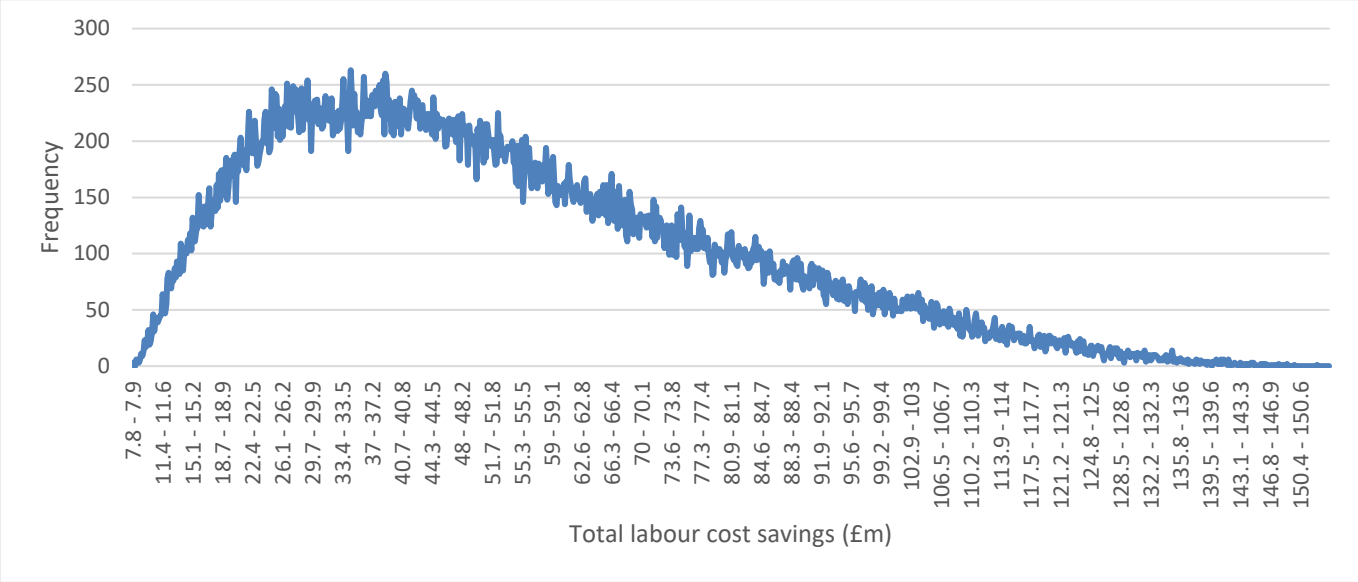
116. As the distribution of likelihood of the assumptions is unknown a uniform distribution is used. Therefore, with a high sample size, the output will trend to the midpoint of the range, for example, 35% for the supervision intensity. However, this analysis will give a useful range of potential benefits.

Option 2	Mean	Minimum	Maximum
Expected benefits – Without uptake assumption	£53.2m	£7.8m	£154.1m
Expected benefits – With uptake assumption	£26.6m	£0m	£140.8m

117. Given the uncertainty of the assumptions the mean shows a £53.2m labour cost saving, with a potential minimum of around £7.8m and maximum of £154.1m. The scale of the savings would cover the monetised costs even under the minimum benefits scenario.

118. With the additional assumption with lower than assumed take up of the regulation change, the Monte Carlo analysis will trend towards 50% (midpoint between 0% and 100%) and the min and max will be close to the min and max. Although the Monte Carlo analysis doesn't help understand this uncertainty, it is better explained that this percentage would scale both costs and benefits rather than potentially making the NPV negative.

Chart 1: Monte Carlo Distribution – Option 2



119. The distribution resulting from the Monte Carlo analysis shows a skew to lower levels of labour cost savings. This is due to the nature of the calculation taking proportions and multiplying them together which typically skews the distribution towards the lower end of the spectrum.

Impact of inflation on community pharmacies

120. Funding for community pharmacy in England was cut by over £200 million between 2016/17 and 2017/18 and has been held flat since throughout the five-year deal. Within the five-year deal, the

Government publicly committed to pursue legislative changes to make better use of the skill mix in pharmacy teams to enable efficiencies in pharmacies to deliver more clinical services.

121. As an illustration, the increase in inflation estimates compared to the forecasts available at the time of the five-year deal in England has resulted in significant unanticipated additional cost pressure falling on the sector. At the time the five-year deal was agreed, it was expected that flat cash would equate to a real terms cut in funding of 9.0% by 2023/24. The most recent inflation estimates[30] suggest that is now 14.6%, equivalent to a further £146m cut in real terms funding.

122. These regulatory changes are expected to help pharmacies be more flexible in dealing with extra cost pressures. However, we expect the decrease in funding to continue to impact negatively on the ability of pharmacy contractors to attract and retain staff and therefore this could hinder the ability of pharmacies to implement the proposed changes in supervision.

Patient safety

123. There is a potential risk to patient safety. The reduced pharmacist supervision could increase the number of errors made. However, this is mitigated by the fact that a pharmacy technician is a registered and regulated healthcare professional in their own right, with education and training to undertake dispensing of medicines. In addition, the pharmacist remains overall responsibility for the pharmacy premises. We are also proposing a transition period before this legislation commences to allow regulatory rules and standards, and professional guidance to ensure good governance safely supports the implementation of this legislation in practice.

Impact on small and micro businesses

124. As these Regulations concern the provision of NHS community pharmaceutical services in the UK on the basis of nationally determined terms of service, it is not possible to differentiate between contractors according to their operational turnover or size. This is to ensure the application of agreed nation-wide standards and practices in the provision of such services as part of the nationally determined contractual frameworks.

125. The regulation changes will remove ambiguity around the term supervision and set out who can supervise the dispensing of items. It is at the discretion of the pharmacy to choose whether to use their pharmacy technicians to make use of the clarified regulation to save pharmacist's time.

126. Although this regulation change applies to all pharmacies equally, it may be more likely to benefit larger pharmacies as they are more likely to employ a pharmacy technician than smaller pharmacies. This could therefore result in a more efficient dispensing process for larger pharmacies.

127. The decision to train pharmacy technicians or other staff will be the decision to incur the cost of training their staff against the benefit of freeing up pharmacist's time which can then be used to complete more services. Additionally, under option 2 there will be pharmacies unable to implement this legislation change or not be able to implement full-time due to not employing a pharmacy technician.

128. Looking at our analysis of the number of companies that the regulatory changes apply to, we have been able to classify them in Table 14. These percentages indicate where a company is impacted by the regulation change. Note if the pharmacy does not employ a pharmacy technician the legislation change will still apply to them. We use England as a proxy as granular business structures data is not available for the other countries.

Table 14: Potential impacts by pharmacy type in England

[30] https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-september-2023-quarterly-national-accounts

Pharmacy Type	Number of pharmacies	Total number of businesses[31]	Regulation change (Option 2)
Independents	1	2,328	100%
Small chain	2-5	527	100%
Larger chain	6-20	92	100%
Small multiple	21-100	22	100%
Medium multiple	101-500	7	100%
Large multiple	501+	4	100%
Total		2,980	

129. If we assume that each pharmacy employs an average of 6 people (based on the HEE workforce survey[32]), this translates into the following number of small and micro businesses:

Table 15: Potential impacts by SME classification in England

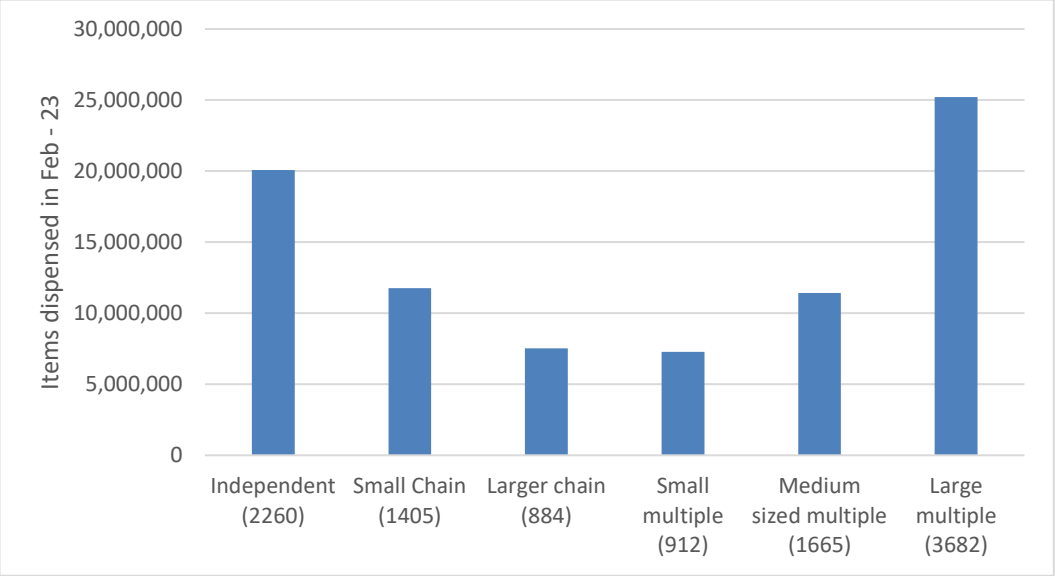
	Total number of businesses	Regulation change (Option 2)
Micro business (1-9 employees)	2,328	100%
Small (10-49 employees)	575	100%
Remainder (50+ employees)	77	100%
Total	2,980	100%

130. As can be seen, the enabling regulation changes will affect all businesses equally.

Wider impacts

131. DHSC only has access to data on pharmacy sizes in England. Using this information, it can be shown that the majority of items dispensed are by large multiples[33] and independent pharmacies. The below graph shows this information with the count of pharmacies in each category in brackets.

Chart 3: Items dispensed in February 2023 by pharmacy size[34]



[31] There were 252 pharmacy stores where we were unable to attribute to a company. We have omitted these pharmacies from the above analysis

[32] The Community Pharmacy Workforce in England 2021 The Community Pharmacy Workforce in England 2021 - survey report_0.pdf (hee.nhs.uk)

[33] Independent (1 Contractor), Small Chain (Contractors 5 or less), Larger chain (Contractors 20 or less), Small multiple (Contractor 100 or less), Medium sized multiple (Contractors 500 or less), Large multiple (More than 500 contractors)

[34] 293 pharmacies were unable to be matched with their size information, these pharmacies dispense around 1.4m items (around 2% of the total) in Feb-23 and have been omitted from the analysis.

132. This change in regulation may impact different types of pharmacies differently, predominately based on their current employment of staff. Although detailed breakdowns of the availability of pharmacy technicians by the pharmacy size is not available, it can be assumed that larger pharmacies have more ability to hire a range of staff and therefore are more likely to benefit from these regulation changes.

133. Given that the costs of the regulation change will only apply to those pharmacies who deem the investment worthwhile, these outlined impacts won't negatively impact pharmacies who currently don't employ pharmacy technicians for example. However, it may enable larger pharmacies to dispense items cheaper than those pharmacies without relevant staff.

134. However, this legislation will ensure pharmacies are using consistent processes as some pharmacies may already be interpreting the ambiguous supervision definition in this way.

Monitoring and Evaluation

135. Making these regulatory changes aims to ensure pharmacy professionals work to the top of their competence and develop more engaging roles for pharmacy technicians as well as other pharmacy staff. As mentioned previously, pharmacies are finding it difficult to fill roles - including pharmacy technicians. For example, in the 2022 England Community Pharmacy Workforce Survey, 60% of respondents found the pharmacy technician role 'fairly' or 'very' difficult to fill. NHSE and DHSC will continue to monitor the annual workforce surveys to consider the headcount and FTE figures for all roles as well as the outputs on vacancy rates. We would hope the monitoring to show an increase in the number of pharmacy technicians.

136. The data on patient safety incidents list will be monitored to consider any changes in volume or severity of harm. However, the data is voluntary, and therefore there are limitations which will need to be considered as it is based on pharmacy contractors reporting their incidents.

137. We will monitor the impact of removing the disparity with locker boxes and distance selling pharmacies. We would expect to see a reduction in patients' complaints and correspondence about the inability to pick up checked prescriptions when the pharmacist is not available or absent.

138. Through ongoing discussion with the sector, pharmacy regulators and professional bodies and the UKs four Chief Pharmaceutical Officers, the Department of Health and Social Care will continue to monitor the effectiveness of the Regulations to ensure they remain fit for purpose and reflect any changes within the sector.

Conclusions

139. Overall, the policy proposals to make legislative changes to the Human Medicines Regulations (2012) and Medicines Act (1968) to make better use of the skill mix in the pharmacy teams have a positive Net Present Value. Option 2 is the recommended option. The level of take up of supervision by pharmacy technicians will be key in achieving the estimated NPV.

140. The proposals are enabling. Pharmacists are not required to authorise supervision to pharmacy technicians, and it will be for each pharmacy to decide if they want to make use of these provisions. We assume a pharmacy contractor will only voluntarily engage with the enabling provisions if favourable to them and generate net benefits.

141. Wider non-quantified benefits are expected from the policy proposal such as a positive impact on the skills mix of pharmacies, the benefits to patients and the reduction in pressure of the NHS of more services delivered in community pharmacy.

ANNEX A: The expanding clinical role of community pharmacies in England

Community pharmacy's expanding clinical role

Pre-2019 offer

mainly dispensing with some limited additional services

- Supply of medicines and other products
- New Medicines Service
- Medicines Use Review (decommissioned in favour of structured medicines review in general practice)
- Self-care
- Signposting
- Healthy living
- Flu vaccination

Additional offer (locally commissioned by NHSE&I or local authorities)

Examples:

- Health checks
- Minor Ailment Service
- Patient Group Directions for skin infection, uncomplicated UTIs, conjunctivitis
- Emergency Hormonal Contraception
- Drug treatment (e.g. supervised) methadone)

CPCF 5-year deal offer

better integrated in the NHS, more clinical services, referrals into pharmacy and first port of call for minor illnesses

Medicines optimisation

- Expanded New Medicines Service
- Discharge Medicines Service (referrals from hospitals)

Urgent care

- Community Pharmacist Consultation Service (referrals from NHS111 and GPs for minor illnesses)

Prevention

- Blood Pressure Checks Service
- Stop Smoking Service (referrals from hospitals)
- Healthy Living Pharmacies

Supported by:

Pharmacy Quality Scheme to drive quality and get ready for changing role

Pharmacy Integration Fund to funding to drive and pilot, integrated delivery models

Covid-19 services

- Medicines Delivery Service
- Pharmacy Collect (LFD tests)
- Increase in flu vaccination (almost 5m in 21/22 versus 1.7m in 19/20)
- Covid-19 vaccination (1,500 sites)

CPCF year 4/5 updated offer

community pharmacy as access point into the NHS (SofS's 'Pharmacy First' ambition)

Strengthen and widen referral routes

- Increase referrals from GPs and hospitals
- Expand Community Pharmacist Consultation Service to Urgent and Emergency Care

Community pharmacy as access point:

- Contraception Management Service (supply and initiation of contraception via Patient Group Directions) –could save 2 million GP appointments/year

NHSE&I pilots (Pharmacy Integration Fund):

- supply of other medicines under Patient Group Directions
- (possibly) direct cancer referrals to hospitals

Encourage Electronic Repeat Dispensing- GP hands management of repeat prescription medicines to pharmacist for up to 12 months.

Covid-19 services

TBC

What is next for community pharmacy?

Urgent Care– Acute conditions

- Increasing the range of treatments available via PGD/prescribing and the number of referrals/walk-in completed in pharmacy

Medicines Optimisation– Managing long term conditions

- Management and initiation of prescription-only medicines for long term conditions (non-complex cased) under a PGD and eventually prescribing (e.g. HRT, high cholesterol or hypertension - where there is a clear first line treatment)
- **Structured Medicines Reviews**– move management of stable/non-complex cases from GP to Community Pharmacy

Prevention

- Point of care testing/Referrals for diagnosis e.g. early signs of cancer
- Planned and opportunistic Health checks (wrapping up different existing and planned/potential service into one service): blood pressure, weight management and diabetes referrals, cholesterol combined with stop smoking, mental health, social prescribing
- Sexual health (contraception, HIV and STI testing)
- Vaccination (flu, Covid-19, pneumococcal, travel vaccinations)