Title: Pharmacist flexibilities **IA No:** DHSCIA9686 **Lead department or agency:** Department of Health & Social Care **Other departments or agencies: N/A**	Impact Assessment (IA) (draft)
	Date: 03/07/2025
	Stage: Consultation
	Source of intervention: Domestic
	Type of measure: Primary legislation
	Contact for enquiries: saira.khan@dhsc.gov.uk

Summary: Intervention and Options

Cost of Preferred (or more likely) Option (base year = year of IA)		
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**
£m	£m	£m

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

Current regulation requires that a pharmacist may not sell or supply a prescription-only medicine "except in accordance with a prescription given by an appropriate practitioner". This has been interpreted to mean that community pharmacists must supply the exact product according to what was prescribed, with some limited exceptions. In some cases, the pharmacy may not hold the stock of medicine to fulfil a prescription straight away meaning that the medicine cannot be supplied to a patient in a timely manner. This in turn has negative impact on patient health, overall quality of care and/or increases administrative burden on pharmacists and prescribers where a new prescription is sought for an alternative product.

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

Improve patient access to medicine in the primary care setting and ensure patient-centred care.
This would apply in instances where a community pharmacist is unable to dispense the medicine on the prescription if it were out-of-stock at the pharmacy.
This could be improved by allowing community pharmacists the flexibility to dispense an alternative strength and/or formulation of medicine if it offers an equivalent treatment and is in the patients' best interest.

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

In principle, there could be various option in which pharmacist flexibilities could be enabled (see paragraph 7 for justification of options below).

Option 1 – Business as usual: Do nothing option will mean no change to patient safety or pharmacy efficiency.

Option 2 – Allow flexibility in limited circumstances: Change legislation to enable pharmacists to dispense alternate strength/formulation (which may also mean a different quantity) of medicine which offers the same treatment in limited circumstances; and it is impracticable in the circumstances to obtain the product in time to meet the patient's needs.

Option 3 – Allow flexibility with no restriction on the circumstances: Change legislation to enable pharmacists to dispense alternate strength/formulation (which may also mean a different quantity) of medicine which offers the same treatment without any restrictions or conditions as to the circumstances.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** N/A

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:** N/A	**Non-traded:** N/A	

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 SELECT SIGNATORY: ..... Date: .....

Summary: Analysis & Evidence

Policy Option 1

Description: No change to the HMRs – medicine dispensing remains as it currently is in that Part 12 of the HMRs in Regulation 214(1); requiring that a pharmacist may not sell or supply a prescription only medicine "except in accordance with a prescription given by an appropriate practitioner".

FULL ECONOMIC ASSESSMENT

Price Base Year 2025	**PV Base Year** 2025	**Time Period Years**	**Net Benefit (Present Value (PV) (£m)**		
			Low: £0	**High: £0**	**Best Estimate:** £0

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

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.

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	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

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

Distributional impacts

N/A

Key assumptions/sensitivities/risks	**Discount rate (%)**
N/A	

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:		
Costs: £0	**Benefits:** £0	**Net:** £0

Summary: Analysis & Evidence

Policy Option 2

Description: Introduce amendments to Part 12 of the HMRs, enabling pharmacists to dispense alternate strength/formulation (which may also mean a different quantity) of medicine which offers the same treatment in limited circumstances e.g. when the medicine on the prescription is out of stock at the pharmacy, there is an immediate need for the prescription-only medicine, and it is impracticable in the circumstances to obtain the product in time to meet the patient's needs.

FULL ECONOMIC ASSESSMENT

Price Base Year 2025	**PV Base Year** 2025	**Time Period Years**	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** TBC

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

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

Costs to implement the legislation and produce standard operating procedures within community pharmacies.
Cost saving to prescriber and pharmacist time in not having to arrange a new prescription or liaise with the patient when they return for a second time.
Cost saving to the patient not having to return to the pharmacy when the medicine becomes in stock.
Pharmacies choosing to make upgrades to their IT systems.
The limited circumstances mean pharmacies should not provide an alternative only if it enabled them to increase their profit but there may be occasions where the alternative does enable them to make more profit.

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

Negative health outcomes due to incorrect dispensing are unlikely due to current low level of dispensing errors.

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

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

Patient: Heath gain to the patient in being able to start a new medication straight away or continue their repeat prescription leading to reduced symptoms or no relapse of symptoms.

Prescriber: Cut down administrative time burden of re-writing prescriptions.

Pharmacist: Reduced administrative burden of: procuring medicine, liaising with the prescriber to get a prescription for an alternative, and liaising with the patient multiple times for one prescription item.

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

Improvement to pharmacist morale as they would be able to provide on-the-spot solution if a medicine is currently out of stock. Reduce pharmacist stress of having to procure one-off medicines or spending time on contacting prescriber or other pharmacies.

Distributional impacts

To be determined post analysis of consultation results.

Key assumptions/sensitivities/risks **Discount rate (%)**

Providing an alternative medicine sooner will have a positive impact on patient health.
There will be minimal impact on the medicine supply chain and pharmacists will abide by the specified criteria.
Prescriber time will be freed up and could be used to cover other clinical work.
Pharmacists will continue to follow professional guidance, where they will act in the best interests of the patient, and that they will maintain medicine ordering patterns as they are currently.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m: To be determined post analysis of consultation results.		
Costs:	**Benefits:**	**Net:**

Summary: Analysis & Evidence

Policy Option 3

Description: Introduce amendments to Part 12 of the HMRs, enabling pharmacist flexibility in dispensing an alternate equivalent medicine without any restrictions or conditions as to the circumstances.

FULL ECONOMIC ASSESSMENT

Price Base Year 2025	**PV Base Year** 2025	**Time Period Years**	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** TBC

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

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

Costs to implement the legislation and produce standard operating procedures within community pharmacy.
Cost saving to prescriber, patient and pharmacist time.
Risk of flexibility being used outside of patients' best interest is increased for this option over Options 1 and 2.
Pharmacies choosing to make upgrades to their IT systems.

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

To be determined post analysis of consultation results.

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

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

Patient: Overall improved patient care and reduced burden on seeking prescription-only medicine from other pharmacies or returning when the pharmacy has medicine in stock.

Prescriber: Cut down administrative time burden of re-writing prescriptions.

Pharmacist: Reduced administrative burden of procuring medicine. Potential increased cost to NHS if the pharmacist uses flexibility only when there is an opportunity to make more profit but no patient benefit.

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

Positive impact on patient safety as the alternative should only be given if suitable, letting patients access their medicine more easily. This would enable them to start or maintain medicines that they require, reducing symptoms. Having an alternative may lead patients to be confused about the medicine dosing regimen.
Improvement to pharmacist morale as they would be able to provide on-the-spot solution if a medicine is currently out of stock. Reduce pharmacist stress of having to procure one-off medicines or spending time on contacting prescriber or other pharmacies.

Distributional impacts

To be determined post analysis of consultation results.

Key assumptions/sensitivities/risks **Discount rate (%)**

Patients could get medicines sooner. However, there is a risk with no conditions attached the flexibility will be used more than is necessary which undermines The Human Medicines Regulations, with less certainty for prescribers as to what their patient received. There are patient safety implications, for example less likely for a second clinical check. Although pharmacists would be expected to continue to follow professional guidance, to act in the best interest of patients, if there are no conditions attached, this increases the risk of pharmacists utilising flexibility or patients requesting flexibility when there is not an urgent need/necessity so increases conflict of interest and risk of utilising flexibility for financial gain. There are significant risks for the medicine supply chain as suppliers predict supply on historical usage and risk of knock-on shortages of the alternative.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m: To be determined post analysis of consultation results.		
Costs:	**Benefits:**	**Net:**

Table of definitions

Term	Definition
Active Ingredient	The component of a drug that is biologically active and responsible for the intended effects, such as treating or preventing a disease or condition.
Community pharmacist	Registered healthcare professionals, regulated by the General Pharmaceutical Council (GPhC), as experts in medicines. The role involves working in a community pharmacy to dispense medicines, written by another prescriber, as well as offer other healthcare services.
Dose	The specific amount of medication administered to a patient at one time or at regular intervals. It is determined by factors like age, weight, and condition. Usually measured in units like milligrams (mg) or millilitres (ml). For example, **500mg** of Paracetamol tablets.
Dosage	A structured plan or schedule for taking medications, often including the specific drugs, dosages, timing, and duration. For example, 2 tablets, four times a day for 5 days.
Drug	Any chemical or biological substance that affects the body and its processes, used in the diagnosis, treatment, or prevention of disease, or to alter bodily functions. For example, **Paracetamol**.
Formulation/ Form	The physical form in which a drug is produced and administered, such as tablets, capsules, injections, creams, or liquids. It includes both active and inactive ingredients. For example, Paracetamol **tablets**.
Prescriber	A licensed healthcare professional authorised to prescribe medications. This includes general practitioners (GPs), dentists, nurse practitioners, pharmacists and other qualified professionals.
Prescription	In the UK, Prescription Only Medicines (POMs) are regulated by the Human Medicines Regulations 2012 which can only be supplied in accordance with a prescription.
Strength	The concentration or amount of active ingredient in a given dosage form (e.g., 500 mg per tablet). It reflects how much of the drug is in each unit.

Evidence Base

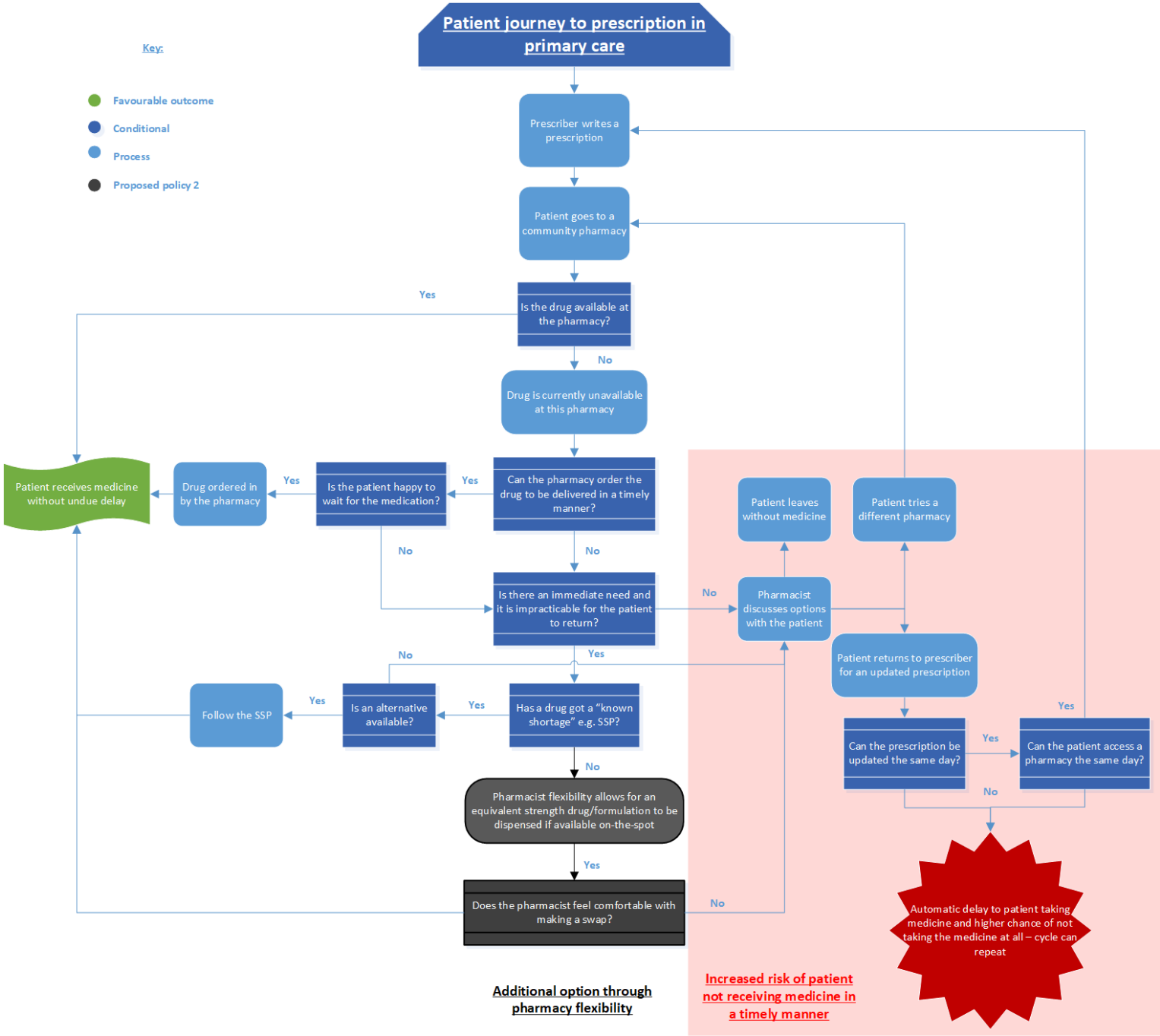
Problem under consideration and rationale for intervention

1. Part 12 of The Human Medicines Regulations 2012 (HMRs) in Regulation 214(1) requires that a pharmacist may sell or supply a prescription only medicine "in accordance with a prescription given by an appropriate practitioner". This has been interpreted to mean that community pharmacists must supply the exact product, quantity, strength and formulation in accordance with what was prescribed. Some limited exceptions include:
   - Where it is practically impossible to dispense the quantity prescribed or very difficult to split the original pack (*e.g. an inhaler*).
   - Prescription is for a valproate containing medicine.
   - Original pack dispensing (OPD) to support patient safety - allowing the pharmacist to supply +/-10% of the original medicine quantity prescribed if it means they can supply an original pack.
   - Supplying an alternative medicine based on the Serious Shortage Protocols (SSPs)[1] .
2. In some cases, the pharmacy may not hold the stock of medicine to fulfil a prescription straight away. Professional guidance[1] states that the pharmacy should then discuss available options with the patient, including:
   - Ordering medicine to be fulfilled the next working day.
   - Checking whether the medicine is available at another local pharmacy.
   - Contacting the manufacturer(s) to check when the medicine will be available.
   - Utilising a Serious Shortage Protocol (SSP), if appropriate.
   - Contacting the patient's prescriber to jointly consider an alternative brand or medicine.

3. Typically, a patient would receive a prescription from a prescriber and go to a community pharmacy. The flowchart below shows the possible steps a patient may encounter when obtaining medicine on their prescription. Occasionally, the medicine still cannot be supplied in a timely manner as shown by the process in the light-red box. The consequences of this vary in severity and include:
   - Impact on the **patient**
     - Making additional trips to the pharmacy to check availability and fulfil prescription.
       - Especially impactful for those in rural areas or with impaired mobility as it may be very difficult to travel to an alternate pharmacy or return to a prescriber.
     - Serious negative health impacts - especially concerning lack of medicine for acute conditions *e.g. antibiotics for an infection.*
     - Frustration leading to loss of trust in pharmacies.
     - Stress involved in seeking an alternate route to access medicine.
   - Impact on the **pharmacy**
     - Extra time spent on discussing alternative options and engaging with patients revisiting pharmacy multiple times about same prescription.
     - Additional stress from handling frustrated patients.
     - Frustration with medicine supply chain and government for lack of solutions.
     - Increased time sourcing medicine if it is unavailable from their usual suppliers.
   - Impact on the **prescriber**
     - Increased administrative time spent on re-writing prescriptions.
     - Additional stress from handling frustrated patients.
   - General **public distrust**
     - Several articles in recent years condemning pharmacies and the government for not providing alternative, available treatments.

[1] The struggle around medicines shortages | General Pharmaceutical Council

Figure 1: Step-by-step patient journey to receiving prescription medicine in primary care



Policy objective

4. The main policy objective is to improve patient access to medicine in the primary care setting and ensure person-centred care. This would apply in instances where a community pharmacist is unable to dispense the medicine on the prescription if it were out-of-stock at the pharmacy. We want to make it clear that this is not about pharmacist prescribing or "generic substitution" (swapping a generic in place of a brand) or providing a different active ingredient to what has been originally prescribed, which would have significant patient safety, conflict of interest and supply chain implications.

5. This could be improved by allowing community pharmacists the flexibility to dispense an **alternative strength and/or formulation** (which may mean a different quantity) of the same medicine originally prescribed and it is in the patients' best interest. We believe that helping patients to receive their medicine as soon as possible will have a positive impact on their health and reduce their worries/inconvenience.

6. We believe that this will also free up prescriber time for other tasks such as providing clinical services to patients as the administrative burden of re-writing prescriptions will be reduced.

Description of options considered

7. In principle, there could be various options in which pharmacist flexibilities could be enabled, with varying degrees of impact on the benefits versus risks on patient safety, conflict of interest and the medicine supply chain. Under option 2, there could be sub-options for example the limited circumstances could only be restricted to clinical or could on be for limited to groups of medicines or certain medical conditions. However, if we restricted the conditions to clinical, then we believe this does not go far enough to support patient access to medicines. On the other end of the spectrum, if we do not attach any conditions, there are real significant risks to conflict of interest and the medicine supply chain. We have considered these carefully and the proposal we are consulting is under option 2 which balances these risks by allowing pharmacist flexibility under certain conditions but goes far enough to be supportive of patient access to medicines. There will often be more than one reason for flexibility to be utilised.

8. **Option 1 – Business as usual:** No change to the HMRs, which means there are no changes to pharmacy or prescriber efficiency or patient safety due to the pharmacist being able to supply an alternative equivalent medicine to fulfil the prescription on the same day. Dispensing would remain as it currently is in Part 12 of the HMRs in Regulation 214(1), requiring a pharmacist to sell or supply a prescription only medicine "in accordance with a prescription given by an appropriate practitioner".

9. **Option 2 – Allow the pharmacist flexibility in certain circumstances:** Introduce amendments to Part 12 of the HMRs, enabling pharmacists to use their professional judgement to dispense alternate strength/formulation (which may also mean a different quantity) of medicine which offers the same treatment in **limited circumstances** explained in paragraph 11.

10. This option would allow the patient to receive an alternative equivalent medicine on the spot at their chosen community pharmacy if the medicine originally prescribed was out-of-stock at the pharmacy. The alternative medicine would have the same total dose of the same active pharmaceutical ingredient to that which the prescriber had prescribed.

11. The following criteria must be fulfilled for the pharmacist to suggest an alternative:
    - Medicine on the prescription is out-of-stock at the pharmacy at the time of patients' visit.
    - The alternative medicine is suitable for the therapeutic need.
    - The alternative medicine suggested is not known to be in serious shortage.
    - There is immediate need for the prescription-only medicine; and/or it is impracticable in the circumstances to obtain the product in time to meet the patient's needs.
        - This would cover medicines needed straight away (*e.g. antibiotics*) and enable the flexibility to be used if returning to the pharmacy would cause serious inconvenience to the patient or leave them without medicine (*e.g. whilst they go on holiday*).

12. Alternative medicine dispensed could include changing:
    - Medicine formulation *e.g. replacing capsules with tablets*.
    - Quantity and strength of individual doses if the sum remains the same *e.g. providing x24 50mg instead of x12 100mg tablets*.

13. **Option 3 – Allow pharmacist flexibility without any restrictions or conditions as to the circumstances**: Introduce amendments to Part 12 of the HMRs, enabling pharmacists to use their professional judgement to dispense alternate strength/formulation (which may also mean a different quantity) of medicine which offers the same treatment without any restrictions or conditions as to the circumstances. This option would allow the patient to receive an alternative equivalent medicine sooner at their chosen community pharmacy. The alternative medicine would have the same total dose of the same active pharmaceutical ingredient to that which the prescriber had prescribed.

14. **For options 2 and 3, we would need to use the enabling powers in Part 2 of the Medicines and Medical Devices Act 2021 ("MMD Act") to allow flexibility around drug formulation and quantity/strength. The proposed flexibilities are optional in that a pharmacist may choose not to provide an alternative.**

15. Note: The proposed policy options 2 and 3 are different to "pharmacist prescribing" where pharmacists would initiate/prescribe treatment autonomously within their clinical competency. Nor would it allow substitution of a different active ingredient, a generic medicine for a branded prescription or controlled drugs listed in schedules 1 to 3 inclusively.

Summary and preferred option

16. **Option 2** is the preferred option as we believe it achieves the objective of improving patient access to medicine through community pharmacy flexibilities whilst balancing the benefits vs risks to patient safety, medicine supply chain and conflict of interest (prescriber vs dispenser).

17. The preferred option will be given effect through secondary legislation. We propose to use the enabling powers in Part 2 of the Medicines and Medical Devices Act 2021 ("MMD Act") to allow flexibility around drug formulation and quantity/strength.

18. We are hoping to evaluate the preferred option based on the results of the consultation which should give us a clearer idea of impacts of the various options and suggest future steps.

19. This consultation would be made available in England, Wales, Scotland and Northern Ireland and the proposed changes to the Human Medicines Regulations 2012 would apply throughout the United Kingdom. Flexibilities impacting NHS prescriptions dispensed in primary care would also require amendments to the Pharmaceutical and local Pharmaceutical Services Regulations (PLPS regulations), in England (and the equivalent in the Devolved Administrations).

Views of stakeholders

20. We have received several calls for pharmacists to be given further flexibilities, including via:
    - The Royal Pharmaceutical Report on "Medicines Shortages"[2] recommends *"flexibility in existing medicines regulations to speed up access".*
    - House of Commons Health and Social Care Select Committee "Pharmacy"[3] report recommends to *"allow pharmacists in community settings to make dose and formulation substitutions for out-of-stock items".*
    - In a "Prevention of future deaths" (PFD) report, which was issued to the Department in January 2025, the coroner expressed a concern that pharmacists are not permitted to provide differing strengths of the same medicines without an amended prescription and a risk that "*future deaths could occur unless action is taken*".[4]

21. Further to these reports, we have spoken to various stakeholders informally and found support for pharmacists to be given further flexibilities, with varying considerations and concerns around the risks versus benefits.

[2] Medicines shortages: Solutions for Empty Shelves, Royal Pharmaceutical Society.

[3] Pharmacy, House of Commons Health and Social Care Committee.

[4] Ava Hodgkinson: Prevention of Future Deaths Report, Courts and Tribunals Judiciary.

Data sources and their robustness

22. In general, there is limited data on the topic of medication dispensing disruptions due to medicine being unavailable in a given pharmacy. This is because there is no pharmacy/prescriber system nor record keeping where failures to dispense medicines, on the same day as prescribed or requested by the patient, is tracked.

23. It is important to note that medicines could be out-of-stock pharmacy for several reasons:
    - National medicine shortage – could include medicines with and without an SSP.
    - Local medicine shortage.
    - Low day-to-day stock of medicines in a pharmacy.
    - Unprecedented increase in medicine demand.

24. Through a literature search we identified a limited number of sources which give us an idea of the impact of medicine shortages on drug dispenses and patient satisfaction; we found no data on other factors mentioned above. Key statistics are reported in the following *Background* section with the full summary referenced in the annex.

25. The statistics referenced in the impact assessment come as a result of surveys, of various sizes, and are based largely on qualitative, and subjective results which would be difficult to compare accurately year-on-year. The data focuses on impacts of national medicine shortages and does not address other factors referenced in paragraph 23. Finally, the data referenced originates from various sources including stakeholder groups which may be biased.

26. The Community Pharmacy England survey[5] was carried out between early March 2024 and early April 2024 consisting of an online questionnaire specifically for pharmacy owners (or head office representatives) and a separate questionnaire for pharmacy team members. Over 900 pharmacy owners – between them representing more than 6,100 pharmacy premises in England – and over 2,000 pharmacy team members (mostly pharmacists, but also some technicians, dispensers and assistants) took part in their respective surveys.

27. The results of the Healthwatch survey[6] come from a Nationally representative poll of adults in England and was conducted in November 2023, with 1,650 responses. Additionally, Healthwatch interviewed 24 pharmacy users and 12 pharmacy members of staff in 12 local areas.

28. Unfortunately, we do not currently know the scale and frequency of the issue i.e. patients not being able to receive prescription medicine on the day that they visit their community pharmacy of choice. We will be looking to use any data provided as part of the public consultation to quantify impacts.

Background

29. There are around 10,500 community pharmacies in England[5] which serve around 1.6 million people every day – more than GP or dentistry teams[5]. From the 2024 Healthwatch survey on pharmacies[6], 72% of the surveyed patients had used a pharmacy in the space of three months. The report says that in England, 80% of people live within a 20-minute walk of a community pharmacy. Demographically, older people are more likely to use a community pharmacy.[6]

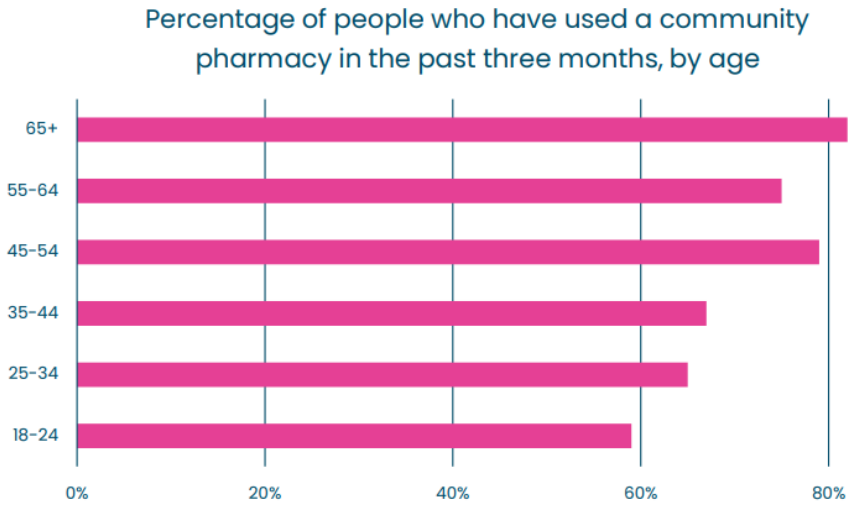


Figure 1 Pharmacy use in a 3-month window by age group.[6]

30. According to a survey ran by Community Pharmacy England[5], where medicines are impacted by shortages, it was most common (43%) for pharmacy team members to spend 1-2 hours a day on sourcing alternative drugs, with 30% spending more than 2 hours, and 21% spending an hour a day. Additionally, 60% of pharmacists make daily contact with GP practices about supply chain issues, with 30% of pharmacists reaching out several times a week. Less than 1% of pharmacists never contact the GP practice.[5]

31. According to Healthwatch survey, in a period of 12 months due to medicine unavailability[6]:
- 42% of people have experienced problems getting medicine from their pharmacy.
- 24% have experienced their pharmacy being out of the medicine(s) they need.

32. Of those who said they have had problems getting medicine from the pharmacy in the past 12 months[6]:
- 55% could not get their medicine the same day.
- 17% got it on the same day by visiting another pharmacy.
- 28% got it on the same day but had to return at another time.

33. The following groups have been considered in the evaluation of the proposed policy: patients, community pharmacists, community pharmacies, NHS, medicine supply chain and prescribers (*e.g. general practitioners and dentists*).

[5] Pharmacy Pressures Survey 2024 Medicines Supply Report, Community Pharmacy England, 2024.

[6] Pharmacy: what people want 2024, Healthwatch.

Monetised and non-monetised costs and benefits of each option (including administrative burden)

Calculations plan

34. We are planning on obtaining information on the frequency of possible policy utilisation and any potential time savings it will involve through the Consultation which will be published alongside this impact assessment. The consultation results and their impacts will be included in subsequent versions of the impact assessment.

35. In the meantime, below is an outline of the method we propose to use to cost the extra time; A, B and C are placeholder scenarios representing a hypothetical range of possible low-middle-high scenarios on extra minutes of Pharmacist time. We will narrow these estimates down via the consultation exercise.

36. £25.42 is the mean average gross hourly pay of a "health professional" (2 digit SOC code 22).[7] Considering other non-wage costs, such as pension and national insurance contributions by the employer, we assumed that the full opportunity cost of time will be the gross hourly rate plus an additional 30% bringing our estimate to £33.05 per hour (£33.05/60=0.55p per minute).

Number of minutes of extra pharmacist time	Cost per minute of Pharmacist time	Total cost of extra pharmacist time
Scenario A (low) 5 minutes	£0.55	£2.75
Scenario B (middle) 10 minutes	£0.55	£5.50
Scenario A (high) 15 minutes	£0.55	£8.25

37. The variables we are going to quantify using the results of the consultation include the following. These will help us assess the current situation and compare it against if flexibilities were in place.

Current variables:	Variables with proposed flexibilities:
Prescriber time to re-write prescription and/or liaise with pharmacy	Pharmacist time to find an alternative and discuss with patient
Pharmacist time to liaise with prescriber and/or patient and/or procure one-off medicine	Frequency at which flexibilities would be used by the pharmacist
Patient time to visit a different pharmacy and/or return to the current one and/or return to the prescriber	
Number of prescriptions encountering issues due to medicine being out-of-stock	

38. Note: The following considerations are based on the assumption that pharmacists will continue to follow professional guidance[8], where they will act in the best interests of the patient, and that they will maintain medicine ordering patterns as they are currently. Any risks to these assumptions have been noted below.

[7] ONS, Annual Survey of Hours and Earnings (ASHE), 2024

[8] Standards for pharmacy professionals, General Pharmaceutical Council.

Risks for different options

39. **Option 1:** 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.

40. The impact on patient safety, medicine supply chain and conflict of interest would remain the same. We do not recommend this option as it does not support increasing patient access to medicine in a timely manner when it is urgently required and whilst the pharmacist has an alternative medicine available.

41. **Option 2:** Anecdotal evidence, from speaking to community pharmacy representative bodies and community pharmacists, suggests that in majority of cases patients are able to receive prescribed medicine in a timely manner as sufficient stock is available at the first community pharmacy they frequent. We know that over 1.2 billion[9] prescription items were dispensed in England in 2023/24 and so the majority of these must be dispensed by pharmacies, processed and reimbursed by the NHS Business Service Authority, in the usual way. This means that Option 2 would apply to a minority of cases, so any financial impact would be minimal. It is possible that the net financial impact could be zero if the possible increase in medicine reimbursement cost to the NHS would be cancelled out with savings to prescriber time.

42. Since the policy would be optional, i.e. pharmacists could choose to not suggest an alternative even if all criteria are met, there will be variability in policy uptake between community pharmacies and pharmacists. We are hoping to gather further insights into this through the public consultation.

43. **Option 3:** As it currently stands, we cannot predict how often pharmacists would choose to provide an alternative medicine to the patient. As the policy would be optional, i.e. pharmacists could choose to not suggest an alternative, there will be variability in policy uptake between community pharmacies and pharmacists. Since there would be no restrictions as to when the pharmacist could provide an alternative, pharmacist flexibilities could be utilised more frequently in Option 3 than 2. This could increase the risk of financial imbalance, with medicine reimbursements outweighing savings to prescriber time and greater risk of destabilising the supply chain if pharmacists provided the same alternatives for the same medicines.

[9] Prescription Cost Analysis – England 2023/24, additional tables, NHS Business Service Authority

Conflict of interest, value for money and patient safety

44. **Option 1:** Under the current arrangements there is a clear separation between the roles of the prescriber and dispenser. This supports patient safety and value for money. The prescriber, who would have access to the patient's medical records, has certainty of what is prescribed and supplied to their patient. The clear separation also means the pharmacist can conduct a second clinical patient safety check, particularly around the appropriateness of the dose for the patient and drug interactions.

45. **Option 2:** If pharmacists were allowed flexibility under specified criteria, the separation between prescriber and dispenser would remain for majority of the cases. This would upkeep high standards of patient safety.

46. Pharmacies purchase products to be dispensed and get reimbursed by the NHS for NHS prescriptions. If the outlined criteria are followed and the patient journey to obtain their medicine is as per the flowchart, it is highly unlikely that pharmacies would be able to use pharmacist flexibility for financial gain as the pharmacist should only provide an alternative in the limited circumstances specified previously. It is expected that NHS prescribers make prescribing decisions that are evidence-based and offer the most cost-effective suitable option for the patient. It is important to note that currently we would not be able to confirm if provision of an alternative medicine was valid as we would not have visibility of *e.g. pharmacy's medicine stock at the time of patient's visit.*

47. By allowing pharmacist flexibility, we would reduce the amount of time prescribers and dispensers spend on liaising with each other and re-writing prescriptions. In turn, it would free up time for prescribers to spend on clinical work. Pharmacists will spend less time on administrative work of procuring medicines or talking to prescribers or patients who return to collect their medicine but may have to spend more time on checking what alternative medicine is suitable and liaising with the patient instead.

48. Anecdotally, this is a common scenario in pharmacies – although there is no evidence as to the exact number of prescriptions referred back to prescribers or patients having to return at a different time. As part of the consultation, we are seeking evidence on how often pharmacists, prescribers and other relevant stakeholders are dealing with minor amendments, in particular returning patients/prescriptions to prescribers to have strength and formulations changes or patients having to return to original pharmacy or visit another pharmacy.

49. By allowing flexibility, we would enable the patient to receive their medicine sooner which could have a substantial positive impact on their physical and mental health. However, an alternative medicine may not be ideal for the patient, for example:
    - Having to take more tablets to achieve the same dose.
    - Difficulties in swallowing if a liquid was prescribed but tablets were dispensed.
    - Change in dosing regimen may be confusing especially if the patient takes other medicines which also have an alternative dosing regimen.
    - Inconsistency of a regular regime medication, especially in complex regimes.
    - Other reasons which the pharmacist and/or patient may not be aware of.

50. It would be down to the pharmacist's professional judgement to assess whether it is suitable to provide an alternative medicine to those who take multiple medicines or have a complex medicine regimen. The pharmacist is expected to weigh up the risks versus benefits of providing an alternative and act accordingly in the patients' best interest according to GPhC professional standards.

51. Currently, pharmacists may not have access to all patient information or know the reason why a patient may have been prescribed a specific product. This increases the risk that the patient would get something that is not suitable for them. The pharmacist would discuss any alternatives with the patient so the overall risk will be minimal and should be outweighed by the number of times it is of benefit to the patient.

52. Option 2 enables pharmacist flexibilities in the following situations where there is a:
- Clinical need – requiring treatment as soon as possible for an acute condition *e.g. antibiotics for an infection.*
- Contextual need – for example, if the patient:
    - Goes on holiday and does not have sufficient repeat medication to last the trip.
    - Will have issues returning to the pharmacy to collect medication on a different day.

53. There may be costs associated with pharmacies choosing to upgrade their IT systems to account for changing provisions. There would also be a cost in pharmacies introducing standard operating procedures (SOPs) and training their staff. Any costs are likely to be one-off (e.g. training) and offset by the time saving. We are seeking evidence on this as part of the consultation. The proposed amendments as part of the consultation are for amending the HMRs only. If these flexibilities were to be introduced for NHS prescriptions dispensed in primary care this would also require amendments to the Pharmaceutical and local Pharmaceutical Services Regulations (PLPS regulations), in England (and the equivalent in the Devolved Administrations) and would involve negotiation with relevant stakeholders including Community Pharmacy England (CPE) and we cannot predict if or what they might ask if in terms of costs.

54. **Option 3:** With no restriction as to when the pharmacist flexibility could be used, increasing the number of times the flexibility could be used, the line between the prescriber and the dispenser blurs, leading to increased risk to patient safety and significant conflict of interest.

55. The same considerations apply as for Option 2 with an increased risk. Since there is no restriction as to when the flexibilities could be used, pharmacies could provide an alternative strength or formulation product when it is not needed, even if the prescribed item is available. This may mean that an alternative medicine can be provided for reasons such as for financial gain. Overall, the safeguards to patient safety are lower for Option 3 than 1 and 2.

56. With this option, pharmacists would **not** need a clinical or contextual reason to suggest an alternative. Some reasons for providing an alternative include:
- If the pharmacy is overstocked in a particular medicine and would like to reduce their stock, particularly if the medicine has a short use-by date – help with medicine wastage.
- Pharmacists being influenced by patients/pharmacy owners/other pharmacists.
- Financial gain.

57. The risk of pharmacists utilising flexibility for anything other than patient benefit is unlikely but not absent. While the General Pharmaceutical Council (GPhC) expects that pharmacists must act professionally and appropriately and not prioritise financial interests and incentives over their patients, there is no restriction with option 3 that there is a patient need. Therefore, we are proposing option 2 as the preferred option as it further minimises the risk that the pharmacist could provide an alternative for anything other than patient benefit. The GPhC can investigate pharmacists for breaching professional standards and take appropriate action.

Impact on medicine supply

58. **Option 1:** No impact on medicine supply. If a medicine is in a known short supply and has an SSP, pharmacists would supply an alternative according to the protocol which takes into consideration stocks on alternatives.

59. **Option 2:** In a shortage, enabling pharmacists to supply an alternative would benefit patients in that moment. There is a risk that the substitution would create a 'knock-on' shortage as the pharmacist is unlikely to have full oversight of overall medicine supply. However, these "knock-on" supply issues could happen anyway if the prescription was changed by the prescriber but with a delay to patient receiving the medicine. This could exacerbate problems with medicine stock availability in pharmacies rather than mitigate supply problems. Some examples of this could include:
    - Depleting stock of lower strength medicine if it is used to make up a higher dose.
    - Using up less frequently used medicines e.g. titrating doses or those reserved for children.

60. The risk to the medicine supply chain is low as pharmacists would not provide an alternative if that alternative is known to be in short supply.

61. **Option 3:** Similarly to Option 2, there would be a risk to the medicine supply. Since pharmacy flexibilities would be unrestricted, the frequency of alternatives being dispensed is likely to be higher. The risk to the medicine supply chain is high especially due to risk of creating knock-on shortages.

62. Currently, suppliers predict future demand primarily based on historic ordering. If pharmacists use the flexibilities habitually or systematically for certain products this could change the demand for each product making it difficult for suppliers to keep up with the changing requirements and hence affect continuity of supply. This would negatively impact continuity of supply with an increased risk to Option 3 over Options 1 and 2.

Internal Market Assessment

63. The Pharmacist Flexibility policy could apply to all of the UK, but it will be for devolved countries to amend their Pharmaceutical and Local Pharmaceutical Services regulations (PLPS regulations). Our assessment is that the proposal would not have an impact on the UK internal market as the objective is to allow pharmacists to dispense an alternative medicine under a prescription. This will be localised at pharmacy level and we do not expect to affect the business-as-usual supply of medicines across the UK. In addition, the proposal is for this policy to be enabling for pharmacies and they will have the option to utilise the increased flexibilities to ease burden on dispensing.

Dispensing doctors

64. None of the proposed options would apply to dispensing doctors.

NHS impact

65. **Option 1:** A delay to patients receiving and taking their medicine may have a negative knock-on effect on the whole of NHS as patients may have a delay in treatment which requires additional medical treatment leading to a poor patient experience.

66. **Option 2**: Alongside how the flexibility will be implemented as part of NHS services, each devolved administration will need to consider the consequences for NHS reimbursement. It is

difficult at this point to consider the impact on NHS spend. However, again taking account of the benefits of reduced administrative burden on pharmacies and prescribers (*e.g. GP* practices), it may be cost neutral or, any change in costs is likely to be marginal. However, we will be seeking views from stakeholders on this as part of the consultation.

67. **Option 3**: The same consideration applies as for Option 2. The impact on the NHS may be higher since the flexibilities are more likely to be used and there is an opportunity for financial gain by the pharmacies which may drive the uptake of flexibilities over patient benefit.

Pharmacy record keeping

68. **Option 1**: Currently, for a pharmacy there is no specific requirement for separate record keeping when a medicine is out of stock. However, under the NHS England Terms of Service for Pharmacists, as set out in The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, pharmacists are required to maintain a record of the medicines provided to facilitate the continued care of the patient. Additionally, they must provide the patient with an estimated time for when the medicine will be ready for collection. These existing requirements help ensure that patients remain informed and that their care is not disrupted due to stock issues.

69. **Option 2**: Where a pharmacist supplies an alternative medicine to that which was originally prescribed, the change should be recorded in the pharmacy's dispensing record (also known as the Patient Medication Record). This would involve the same ways of working as when a medicine is dispensed in Option 1. To enable regulatory bodies to see when the flexibilities have been used and the rationale - consideration needs to be given to record-keeping requirements.

70. **Option 3**: The same consideration applies as for Options 1 and 2.

Notifying the Prescriber

71. **Option 1**: Under the current system, there is a clear separation between the roles of the prescriber and the dispenser. The prescriber has access to the patient's full medical records and makes clinical decisions based on that information. As pharmacists are required to dispense exactly what is prescribed (except in very limited circumstances), the prescriber can be usually confident that the medicine issued matches their records. This supports accuracy in the patient's prescriber medical record, continuity of care, and clinical oversight.

72. **Option 2:** Where a pharmacist supplies an alternative medicine to that which was originally prescribed, this information is not automatically shared with the patient's prescriber. As a result, the prescriber medical record, which reflects what was prescribed and forms part of the patient's clinical history, may no longer reflect what the patient was dispensed. This disconnect could affect ongoing treatment, particularly for patients with long-term or complex needs. To address this, there is consideration of whether pharmacists should be required to notify the prescriber when an alternative is supplied. This would help maintain an accurate, up-to-date clinical record and support safer, more co-ordinated care.

73. As part of this consultation, we are requesting whether there should be a requirement to notify the prescriber.

74. Benefits of notifying the prescriber would be:

- Improved accuracy of the patient's prescriber record.
- Greater transparency and continuity of care between prescriber and dispenser.
- Reduced risk of prescribing errors in the future.
- Supports better-informed clinical decisions for future treatment.

75. Possible cons would be:
    - Increased information flow to prescribers and increased administrative burden for pharmacists and prescribers.

76. **Option 3:** The same consideration applies as for Option 2. However, under Option 3, the importance of notifying the prescriber may be higher since the flexibilities are more likely to be used. Requiring notification under this option could help maintain accurate records and support safer, more co-ordinated care.

Short summary of considerations

77. Below we include summary of possible outcomes for various stakeholders. The impacts remain the same as they currently are for Option 1.

Option 2	Positive	Negative
Patient	• Increase the likelihood of receiving medicine sooner and in a single pharmacy visit. • Overall improved patient care. • Reduced time/money spent on making multiple trips to prescriber/pharmacy.	• Additional time to discussion of medicine, especially if they had just spoken about it to their prescriber. • Confusion around change of dose – disruption in drug regime. • Negative health impacts due to unforeseen side effects.
Prescriber	• Cut down administrative time burden of re-writing prescriptions.	• Lacking visibility of drug changes – *to be confirmed post analysis of consultation results*.
Pharmacist	• Cut down administrative time burden of sourcing medicine. • Reduce likelihood of negative interactions with patients. • More able to act in the patients' best interest.	• One-off administrative burden of familiarisation. • Possible administrative burden of recording what was dispensed. • May not feel confident or put under pressure to provide an alternative drug. • Dealing with frustrated patients if cannot provide an alternative medicine on certain occasions.
Pharmacy	• Reputational improvement if patients are happy with alternative equivalent medicine. • Could financially benefit from providing an alternative.	• Reputational damage/business loss if it is known as a pharmacy which does **not** provide alternatives.
Medicine supply chain	• Ease demand on certain drugs if alternatives could be dispensed.	• Cause supply issues for alternative drugs. • Reduce suppliers' ability to model future demand.
NHS	• Better patient access to medicines and avoiding needing further treatment. • In some cases, reimburse medicine at a lower cost.	• In some cases, reimburse medicine at a higher cost.

Considerations for Option 3 are the same as for Option 2 but with exacerbated results – see main text for a complete explanation.

Monitoring and evaluation

Baseline Understanding and Initial Limitations

77. In general, there is limited data on the topic of medication dispensing disruptions due to medicine being unavailable in a given pharmacy. This is because there is no pharmacy/prescriber system nor record keeping where failures to dispense medicines, on the same day as requested by the patient, is tracked. This limits our understanding of the baseline problem.

78. Existing data is largely anecdotal and stakeholder-driven, with no systematic monitoring in place. This lack of a robust baseline presents challenges in estimating the policy's potential costs, benefits, and savings. Current prescription cost analysis data from NHS BSA covers only the items which have been dispensed, not those which were prescribed. If we knew how many prescriptions go unfulfilled currently versus post policy implementation, we could get an indication of whether the policy may have had an impact on patients access to medicine.

79. To assist us in understanding the baseline problem, an initial consultation will be conducted to gather qualitative and quantitative insights from key stakeholders: patients, prescribers, pharmacists and their representative bodies. Care will be taken to mitigate potential biases by comparing data from multiple groups.

Policy Uptake and Natural Filtering

80. The policy is designed to be enabling rather than mandatory. Pharmacies are likely to adopt flexibilities when it aligns with their operational and patient care interests. This self-selecting mechanism reduces the risk of unintended costs: if the policy is not used, the system defaults to business-as-usual (BAU) (Option 1), incurring no additional expenditure. Conversely, when the policy is used, it is likely because it offers clear benefits to both pharmacists and patients. This built-in incentive structure provides a natural filter for beneficial use.

Prescription Data Monitoring

81. Depending on the final implementation, there may be mechanisms to track when an alternative medicine strength or formulation is dispensed. For example:
    - NHS BSA may be able to identify and record when an alternative medicine was dispensed.
    - Contacting integrated care boards (ICB) to check whether they have records of what is prescribed to compare with what was dispensed to gather substitution trends.

    These data sources will be explored where feasible to track policy usage over time.

Stakeholder Engagement and Qualitative Assessment

82. We will maintain engagement with relevant stakeholders such as Community Pharmacy England to assess the perceived impact of the policy on workload, patient outcomes, and operational efficiency. Additionally, we will monitor periodic publications from stakeholders such as the yearly *Pharmacy Pressure Survey* from CPE.

Annex

Community Pharmacy England (CPE) – *Pharmacy Pressures Survey 2024* [5]

83. Pharmacy Pressures Survey 2024 from CPE represents all 10,500 community pharmacies in England. The survey was carried out between early March 2024 and early April 2024 consisting of an online questionnaire specifically for pharmacy owners (or head office representatives) and a separate questionnaire for pharmacy team members. Over 900 pharmacy owners – between them representing more than 6,100 pharmacy premises in England – and over 2,000 pharmacy team members (mostly pharmacists, but also some technicians, dispensers and assistants) took part in their respective surveys. The following results have been collected for the various groups.

Pharmacy team members:

- 97% report patients being inconvenienced as a result of medicine supply issues.
- 79% report that patient health is at risk due to medicine supply issues.
- 98% report that more partial dispenses had to be issued, with patients having to return to the pharmacy another time to collect the rest of their medication.
- 99% of pharmacy team members are encountering medicine supply issues at least weekly, and 72% now face multiple issues a day.
- 97% report extra workload, and 96% report additional stress for staff as a consequences of medicine supply issues.
- 84% said medicine supply issues had led to patient aggression in their pharmacy.

Business owners:

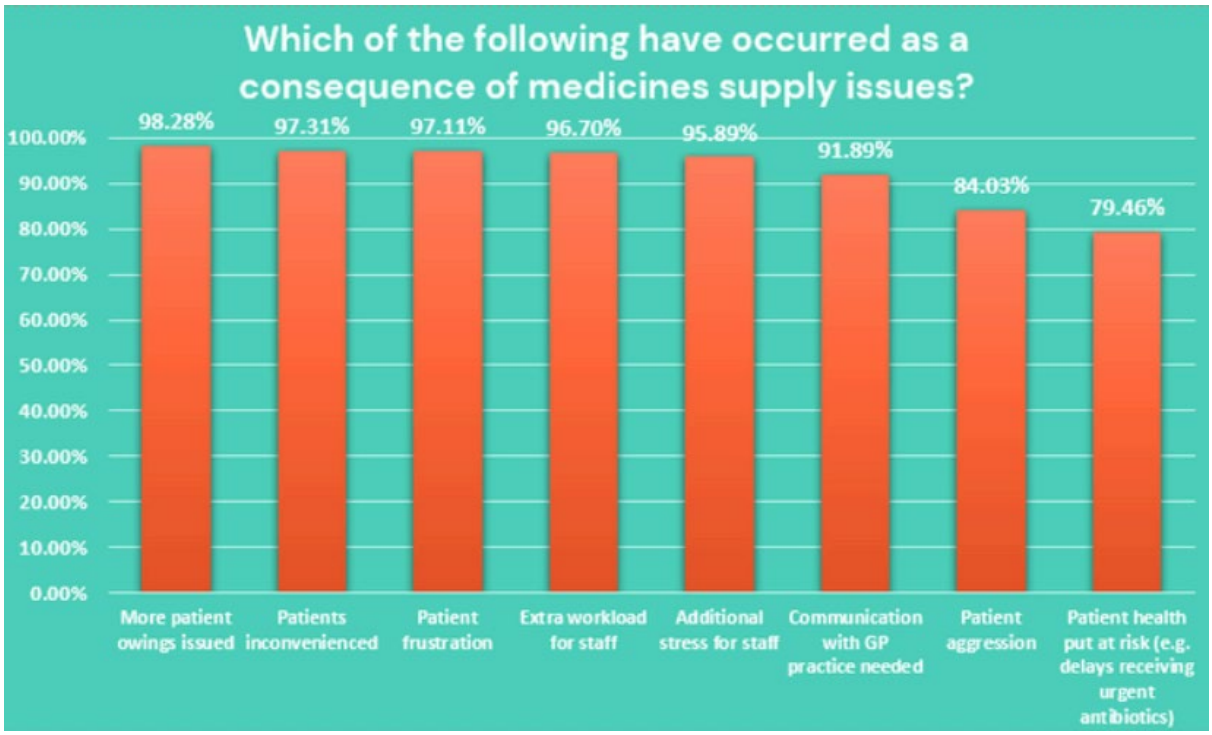
- 91% report that their business is experiencing a significant increase in medicines supply chain/wholesaler issues compared to last year.
- 57% of business owners report that their business is seeing a significant increase in the number of patients who have already visited another pharmacy, since last year. A further 32% report a small increase.
- 94% report that their teams now spend more time sourcing medicines compared to last year, and 84% say their teams are spending longer than ever before sourcing medicines.
- Pharmacy business owners list their top 3 highest worries, starting from the top, as: finances, medicine supply, and team well-being.

84. It was most common (43%) for pharmacy team members to spend 1-2 hours a day on sourcing alternative drugs, with 30% spending more than 2 hours, and 21% spending an hour a day.

85. For 60% of pharmacists, they make daily contacts with GP practices about supply chain issues, with 30% of pharmacists reaching out several times a week. Less than 1% of pharmacists never contacts the GP practice.

86. In 2024 medicines frequently affected by shortages were those for: the treatment of diabetes, ADHD, and epilepsy.

87. In 2023, there were supply chain and availability issues with the following drug types: Hormone Replacement Therapies (HRT), adrenalines and antibiotics.

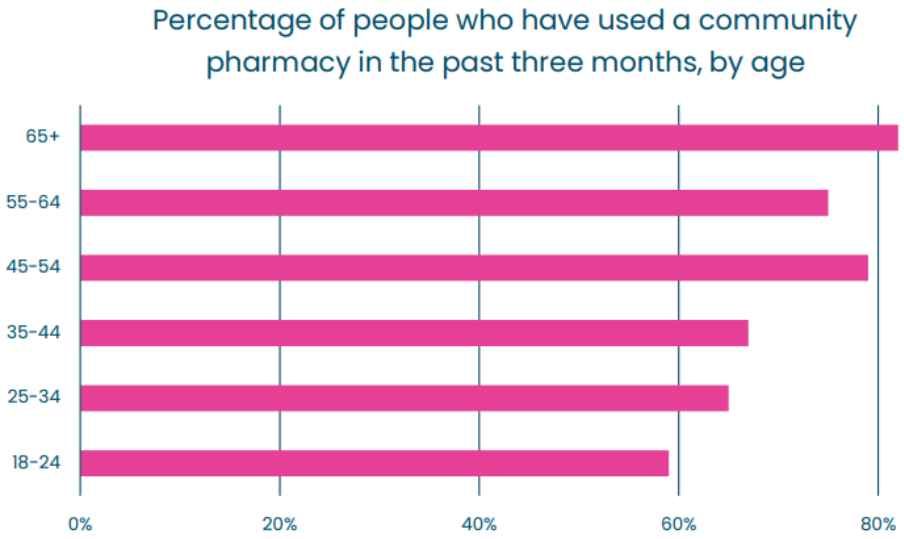

Which of the following have occurred as a consequence of medicines supply issues?
100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
98.28%
97.31%
97.11%
96.70%
95.89%
91.89%
84.03%
79.46%
More patient owings issued
Patients inconvenienced
Patient frustration
Extra workload for staff
Additional stress for staff
Communication with GP practice needed
Patient aggression
Patient health put at risk (e.g. delays receiving urgent antibiotics)

Healthwatch – *Pharmacy, what people want 2024* [6]

88. Community pharmacies are very widely used, with 72% of people having used one in the past three months. In England, 80% of people live within a 20-minute walk of a community pharmacy which serve around 1.6 million people every day – more than GP or dentistry teams.

89. The results of the survey come from a Nationally representative poll of adults in England was conducted in November 2023, with 1,650 responses. Additionally, Healthwatch interviewed 24 pharmacy users and 12 pharmacy members of staff in 12 local areas.

90. Impact on demographics:
A greater proportion of older people have experienced shortages than younger people. Three in ten (30%) of those over 65 said they had a problem getting medicine in the last year because of shortages, compared to 15% of people aged 18-24. This is likely a reflection of older people making more use of pharmacies.



91. The medicine shortages affect women more than men. Over a quarter (26%) of women have had problems getting medicine in the past 12 months because of shortages, compared to 22% of men. This may be explained by the well-publicised shortage of (HRT), used to relieve the symptoms of menopause.

92. In general, in the past 12 months due to medicine unavailability:
- 42% of people have experienced problems getting medicine from their pharmacy.
- 24% have experienced their pharmacy being out of the medicine(s) they need.

93. These numbers are likely to be an underestimate as more people may not have been aware that difficulty in obtaining medicine was due to supply shortages/availability.

94. Of those who said they have had problems getting medicine from the pharmacy in the past 12 months:
- 55% could not get their medicine the same day.
- 17% got it on the same day by visiting another pharmacy.
- 28% got it on the same day but had to return at another time.

95. Two-thirds (66%) of people over 55 who had problems getting medicine were not able to get it the same day, compared to a third (33%) of people aged 18-24, demonstrating that medicine shortages are disproportionately an issue for older people.

Other considerations:

- 7% of people had problems getting medicine from the pharmacy in the past 12 months because it was unexpectedly closed when they got there. This is a higher risk for pharmacies with a single pharmacist as legally the pharmacy can only be open if a pharmacist is on the premises.
- Some pharmacists have good working relationships with local GP practices, but others said they often do not.