Title: Adding Pharmacy Technicians to the list of registered health professionals able to supply and/or administer medicines under Patient Group Directions (PGDs). **IA No: 9597** **Lead department or agency:** Department of Health & Social Care **Other departments or agencies:** NHS England, Medicines and Healthcare products Regulatory Agency	**Impact Assessment (IA)** **Date:** 24 April 2024 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** medicines.mechanisms@dhsc.gov.uk

Summary: Intervention and Options

RPC Opinion: Out of scope

Cost of Preferred (or more likely) Option (in 2019 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
£1.9bn (tentative)	Voluntary measure	Voluntary measure	Not applicable

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

The aim of this policy is to support NHS ambitions by including PTs in the list of registered health professionals able to supply and/or administer medicines under PGDs. Pharmacy technicians (PTs) are not included in the list of qualified healthcare professionals authorised to supply and/or administer medicines under a Patient Group Direction (PGD), despite having the potential to acquire the necessary skills/knowledge within their role as registered healthcare professionals. The use of PGDs by PTs will support the ambitions of NHS systems across GB, to further integrate community pharmacy into the NHS. It will do this by allowing a greater range of patient facing services to be offered in community pharmacy as PTs will be able to supply/administer medicines using a PGD in provision of clinical services. This will contribute to freeing capacity in other parts of the healthcare system and supports pharmacies to become the first port of call for minor illness. Outside of community pharmacy, this proposal allows PTs to be further utilised as part of the workforce, so they can add greater value to multi-disciplinary teams. Currently, PTs cannot operate under a PGD which limits the support they can provide in the safe and effective supply/administration of medicines and provision of clinical services. This creates additional costs to pharmacies, potential delays to patients and inefficiencies within community prescribing teams. Government intervention is necessary to change legislation, improve flexibility and address these concerns in a safe/effective manner.

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

- Improved patient experience and care.
- Improved efficiency and cost effectiveness.
- Provide clearer lines of clinical responsibility.

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

- Option 0 Do Nothing – Preserves existing roles and responsibilities.
- Option 1 – Adding Pharmacy Technicians to the list of registered health professionals able to supply and/or administer medicines under (PGDs). This is the preferred option.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Review due July 2025.

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

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister: Andrea Leadsom Date: 24 April 2024

Summary: Analysis & Evidence Policy Option 1 – Proposed Change

Description: Allow Pharmacy Technicians to supply/administer medicines under PGDs

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2023	Time Period Years 10 Years	Net Benefit (Present Value (PV)) (£m)		
			Low: £0.3bn	High: £5.3bn	Best Estimate: £1.9bn

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low			£0.7bn
High			£11.0bn
Best Estimate			£3.9bn

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

PTs will require training to use PGDs but can choose whether to take up the opportunity. Uptake of training is uncertain, with a range of 25%-100% uptake considered to provide sensitivity. The training is free, but the opportunity cost will be borne by PT employers.

Expanding the role of PTs may reduce their capacity for other work, suggesting an associated opportunity cost to their employers. This will vary significantly depending on the PGDs introduced and the proportion of the profession who undertake additional PGD training. As such we use a range of scenarios to demonstrate the scale of potential opportunity costs.

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

Administrative costs associated with developing and reviewing PGDs may vary given the potential for wider use. Recruitment and salary costs for PTs may be affected slightly in line with experience and responsibilities. These costs are expected to be relatively low compared to the monetised elements and would be borne by local organisations developing and reviewing PGDs.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low			£1.0bn
High			£16.3bn
Best Estimate			£5.7bn

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. The scale of this benefit is uncertain and will vary depending on the specific PGD and the proportion of the profession who undertake additional PGD training. Given this, we have assessed a range of scenarios, varying the estimated time currently spent by pharmacists supplying and/or administering medicines using PGDs as well as the proportion of this which could be delegated to PTs.

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

Improved patient satisfaction with the process of accessing medicines, due to reduced delays.

Improvements to patient health resulting from more timely access to medicines.

The extent of these benefits will be proportional to the demand for PGDs but should exceed the costs given the voluntary nature of the new rules.

Key assumptions/sensitivities/risks	Discount rate (%)	1.5%

There are potential risks with extending medicines mechanisms to further regulated healthcare professionals. Most are not unique to PTs but include possibly increasing dispensing errors and benefits only impacting some patients due to limitations with PGD mechanisms. Mitigating actions have been factored in.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m: n/a			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	Benefits:	Net:	Not applicable (voluntary measure)

Evidence Base

Problem under consideration and rationale for intervention

1. Pharmacy technicians (PTs) are involved in the procurement, storage, supply and preparation, administration and education of medicines and medicinal products. Indicative scenarios demonstrating the scope of PTs activities are described in paragraphs 40-48.

2. PTs are not included in the list of qualified healthcare professionals authorised to supply and/or administer medicines under a Patient Group Direction (PGD). A PGD is a written instruction that enables certain qualified healthcare professionals to supply and/or administer medicines to a pre-defined group of patients without them having to see a prescriber (e.g. doctor, pharmacist or nurse prescriber). PTs can use their registered status and initial education and training to supply and administer medicines, including consenting patients but currently must refer to a prescriber for aspects they could deliver safely via PGDs. This may create delays in patient care and does not utilise the skill mix within pharmacy teams.

3. This proposal is part of the continued policy ambition to extend the medicines mechanisms to registered healthcare professionals. NHS England has recognised that this policy ambition continues to improve patient choice and access to medicines while also developing the workforce to support an expectation that patients can be cared for and treated by the most appropriate healthcare professional. This enables the medical workforce to treat more complex cases.

4. The use of PGDs by PTs will support the ambitions of NHS systems across England, Wales and Scotland, to further integrate community pharmacy into the NHS. It will do this by allowing a greater range of patient facing services to be offered in community pharmacy as PTs will be able to supply/administer medicines using a PGD in provision of clinical services. This will contribute to freeing capacity in other parts of the healthcare system and supports pharmacies to become the first port of call for minor illness. Outside of community pharmacy, this proposal allows PTs to be further utilised as part of the workforce, so they can add greater value to multi-disciplinary teams.

5. PTs are not a regulated profession in Northern Ireland and as such, this reform would not apply in NI without additional changes to the rules. However, it would help facilitate any such change in future.

Policy objective

6. The aim of this policy is to support NHS ambitions by including PTs in the list of registered health professionals able to supply and/or administer medicines under PGDs. This policy contributes to the ambitions of NHS systems across GB, 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.

7. Enabling PTs to use their skills and knowledge to undertake more clinical services via a PGD will enable pharmacists to focus their clinical expertise and prescribing skills to support better patient outcomes. Allowing PTs to use PGDs may increase capacity of another registered workforce, expanding patient access to services. This may reduce the need for appointments in other parts of the Healthcare System, such as GPs and Urgent and Emergency care.

8. Enabling PTs to use PGDs should also allow patients to access a wider range of services convenient to them by healthcare professionals with the right level of skills at the right time, enabling patients to collect their medicines from community pharmacies during times convenient to them.

9. It is a government priority to strengthen the future NHS workforce and the skill mix in community pharmacy. NHS England and the Association of Pharmacy Technicians UK have been prominent in the work to develop this proposal.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

10. This reform may affect a large number of pharmacy technicians, and by extension other pharmacy clinicians and patients. This increases the level of costs and benefits expected. Nevertheless, it is voluntary in terms of uptake. Nor is a reallocation of responsibilities to improve efficiency and patient outcomes particularly novel. As such, a medium level of analysis is appropriate under the proportionality approach.

11. The Impact Assessment uses the best available data and evidence to assess the likely impacts. Nevertheless, the available data are limited, particularly around the expected level of uptake of the new training and around current staffing flexibilities. To help address this, and as part of wider discussion with stakeholders, the proposals were the subject of a public consultation on 18 August 2023 with a summary of the resultant findings published on 28 March 2024.[1]

12. The consultation was positive about the proposals generally (84% in favour) but respondents did identify a number of concerns and questions, and/or provided further information. The impact assessment has been updated in the light of that feedback. Uncertainty does remain about the precise size of some impacts, but the replies provide confidence that the overall effect will remain positive where the option to apply the new rules is taken up.

13. Given the data limitations we have continued to use a range of indicative scenarios to demonstrate potential situations where the policy change may be expected to provide benefits. The precise level of impact will depend on uptake of the new flexibilities, the volume of PGDs undertaken by PTs and the time spent training and monitoring staff.

Description of options considered

Option 0 – No Change

14. PTs can continue to supply and/or administer medicines under a pharmacist's supervision where medicines have been prescribed under a Patient Specific Direction (PSD). This will preserve existing roles and responsibilities but does not create extra capacity in primary and secondary care, or address the concerns identified.

Option 1 (preferred) – Adding Pharmacy Technicians to the list of registered health professionals able to supply and/or administer medicines under PGDs (in GB).

15. Currently, PTs are unable to supply and/or administer medicines without a PSD which still requires an assessment by an authorised prescriber. This may result in delays for patients who want to access medicines and does not fully utilise the skill mix in pharmacy teams.

[1] https://www.gov.uk/government/consultations/proposal-for-the-use-of-patient-group-directions-by-pharmacy-technicians

PTs are not currently included in the list of qualified healthcare professionals authorised to supply and/or administer medicines under a PGD, despite having the potential to acquire the necessary skills/knowledge within their role.

16. The reform will allow PTs to use PGDs, enabling them to supply and/or administer medicines to pre-defined groups of patients without them having to see a prescriber (e.g. doctor, pharmacist or nurse prescriber). The policy is expected to have the following benefits:

    a. **Improved Patient Experience and Care** – Patients who are provided pharmaceutical care by PTs could receive the treatment they need without additional appointments or delays to see a prescriber to receive their medicines. This may improve patient care by reducing the time taken to access healthcare professionals who are able to autonomously treat and supply medicines to the patient.

    b. **Improved Efficiency and Cost Effectiveness** – PTs could supply and/or administer medicines without requiring the intervention of doctors and other health professionals. This is expected to increase efficiency of service delivery by maximising appropriate use of all professionals in the team. Furthermore, if PGDs increase the capacity of early health interventions (e.g. vaccinations) this may reduce the need for more costly health interventions in the future, improving cost effectiveness.

    c. **Clearer Lines of Clinical Responsibility** – PTs frequently need to request an independent prescriber to prescribe medicines for the patients they are caring for, or to seek the help of another healthcare professional who has not undertaken the same level of medicines-specific education and training to supervise consent. This policy would enable PTs to take responsibility for their decisions to administer and/or supply medicines in accordance with the written PGD. The PGD provides a clear scope of practice with specific education and governance requirements defined by appropriate clinical governance assurance processes.

17. This proposal is enabling and designed to give the NHS an additional option for delivering medicines. Commissioning PGDs for use by PTs would be optional, to be determined at a local level depending on patient need and service requirements.

Costs

Training Costs

18. It is essential that all activity is performed by properly trained and qualified clinicians. The consultation noted that not all PTs would have the necessary experience or ability and might need time before they were ready to take on additional responsibilities. The reform acknowledges this and includes several safeguards. There is a two-year programme of pre-requisite training and experience to become a qualified PT, and once that is achieved, a decision will be taken by local managers on when and whether a PT is ready to apply for additional PGD-specific training. If a PT is not judged ready, then they would continue to develop in the normal way and any PGD use would remain in the hands of experienced staff.

19. In line with NICE Guidance, additional on-line training (using the eLfH programme available from the Specialist Pharmacy Service) will be required for PTs to understand the

mechanism to use PGDs.[2] This training already exists, is free to access and is estimated to take approximately 3 hours.[3] Costs of backfill for this time (to capture either the financial cost of backfilling staff or the economic cost of reduced activity) is based on a unit cost of £37.00 per hour (PSSRU Band 4 Unit Costs[4] which includes both wages, oncosts and overheads). Some more experienced pharmacy technicians may be on Band 5 (£42 per hour)[4] which would add to the cost estimate. It has not been possible to model the proportion of eligible staff at each band in detail, and so we have retained the £37 per hour rate for estimation purposes. In practice, this may understate the costs slightly.

20. DHSC estimates the cost at which QALYs are gained at the margin to be £15,000, relative to their societal value of £70,000, a multiplier of 4.7 (£70,000 / £15,000). Therefore, diverting resources towards training results in an opportunity cost. Taking this into consideration, the social opportunity cost of training per PT is estimated to be £518.00 (£37.00 wage unit cost per hour x 4.7 multiplier x 3 hours). This cost will be borne by local organisations (typically pharmacies) employing PTs.

21. Some PGDs may have additional skills requirements on top of the basic training, depending on the specific circumstances. In all cases, local managers will have discretion over who carries out PGD activity, and thus ensure that all qualifying criteria are met. It is not the case that the reform will allow all PTs to handle all PGDs.

22. Training is voluntary and as such the uptake and timing of training is uncertain. Given this, we have assessed a range of options, varying uptake from 25% to 100% of all registered PTs in England, Wales and Scotland. (As of 2022 there were 24,439 PTs registered in England, Wales and Scotland; we assume the number of PTs trained to be between 6,110 and 24,439 in total over the ten-year appraisal period).[5] We further assume that of those who seek training, 50% are trained in the first two years following the proposal with the timing of training for the remaining PTs being linear over the remainder of the appraisal period in each scenario; the total undiscounted cost of training over 10 years is estimated between £3.2m - £12.7m. Discounting training costs at 1.5%[6] results in a discounted training cost over 10 years between £3.0m - £11.9m.

23. This estimate is uncertain and quite wide-ranging. No growth or turnover effects have been applied to the profession over time. Training time may vary from 3 hours as there is no time limit.[7] Potential compliance costs associated with training have been assumed to be negligible. Overall, the training remains optional. Assuming people only use it when they or their employer feels it is worthwhile, there should be a net benefit on an individual case basis, justifying the training cost.

Other Costs

24. There may be an additional marginal cost resulting from developing and authorising PGDs for PTs. The time to develop and review PGDs may vary significantly depending on the

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[2] Specialist Pharmacy Service. Patient Group Directions eLearning Programme. 2021. https://www.sps.nhs.uk/articles/patient-group-directions-e-learning-programme/#:~:text=This%20e%2Dlearning%20programme%20has,Care%20Excellence%20(NICE)%20guidance. https://www.e-lfh.org.uk/programmes/patient-group-directions/.

[3] Derived from discussions with Specialist Pharmacy Service.

[4] Personal Social Services Research Unit Costs of Health and Social Care 2022 (https://www.pssru.ac.uk/unitcostsreport/). Page 60.

[5] General Pharmaceutical Council. The GPhC register as of 31 May 2022- Trend Data. gphc-register-trend-data-may-2022-.docx (live.com)

[6] HM Treasury. The Green Book (2022). https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government/the-green-book-2020#a6-discounting

[7] Specialist Pharmacy Service. Patient Group Directions eLearning Programme. 2021. https://www.sps.nhs.uk/articles/patient-group-directions-e-learning-programme/#:~:text=This%20e%2Dlearning%20programme%20has,Care%20Excellence%20(NICE)%20guidance. https://www.e-lfh.org.uk/programmes/patient-group-directions/. Derived from discussions with Specialist Pharmacy Service.

PGDs content and complexity, and by their volume, and it has not been possible to provide a robust monetised figure. Reviews of PGDs, and their associated costs, are expected to occur at least every 3 years following NICE guidelines and such monitoring will help confirm whether any improvements can be made.[8]

25. A few consultation respondents identified recruitment costs for employers being impacted. This could imply an additional overhead cost on top of backfilling any time spent dealing with PGDs. At the same time, training costs need only be incurred once, such that recruiting people with training would have benefit to the recruiter.

26. Salary costs for PTs were also highlighted as a potential issue. It is possible that the acquisition of additional skills and responsibilities may affect PTs suitability for a pay increment, and that additional responsibilities without additional pay might act as a disincentive. We have no evidence to estimate the size of these effects. However, even with a potential cost pressure, it would still be more cost-effective for a qualified PT to administer PGDs than a more experienced pharmacist. As such, the rationale behind the reform remains unchanged, and so too does the discretionary nature of the additional training offer. We have not been able to monetise any salary impact but believe it would not be sufficient to affect the overall positive outcome.

Existing PT Responsibilities

27. Expanding the role of PTs may affect their existing roles and responsibilities. Increased responsibilities may be at the detriment of existing activities, resulting in worse patient outcomes and an inefficient use of resources. The consultation noted concerns about staff shortages, workload and time. It might also be true that a wider range of work might be viewed positively, but either way there will be an opportunity cost associated with the displacement of current PT activities.

28. We assume this social opportunity cost per hour a PT spends using PGDs (to capture either the financial cost of backfilling staff or the economic cost of reduced activity) is valued at £172.67 per hour (£37.00 wage unit cost per hour[9] x 4.7 multiplier), following the methodology detailed under training costs above. The scale of this opportunity cost will depend on the extent to which activities currently undertaken by other healthcare professionals are delegated/undertaken by PTs. This is uncertain and will vary depending on the specific PGDs introduced and the proportion of the profession who undertake additional PGD training.

29. Given this, we have assessed a range of scenarios, varying the estimated time currently spent by pharmacists supplying and/or administering medicines using PGDs as well as the proportion of this time which could be delegated to PTs. We vary the proportion of time currently spent by pharmacists using PGDs from 25% - 50% of hours worked, although uncertain, this equates to 409 – 818 hours per year per pharmacist. We assume between 25% - 50% of these activities may be delegated to trained PTs, resulting in 102 – 409 hours spent per year per PT using PGDs. We acknowledge this is highly uncertain and will vary significantly across pharmacies. The consultation did not provide more robust data, although a majority of respondents (83% of those expressing an opinion) agreed that the IA assumptions were reasonable, albeit uncertain. The reality is that the time involved will vary with each individual case.

[8] NICE Patient Group Directions. https://www.nice.org.uk/guidance/mpg2/chapter/recommendations

[9] Personal Social Services Research Unit Costs of Health and Social Care 2022 (https://www.pssru.ac.uk/unitcostsreport/). Page 60.

30. Combining these assumptions with our assumptions for training the profession detailed in the training costs section above, the total undiscounted social opportunity cost of expanding PTs responsibilities over 10 years is estimated between £754.6m - £12.1bn. Discounting costs at 1.5% results in a discounted cost over 10 years between £687.0m - £11.0bn.

31. This estimate is highly uncertain. The decision for a PT to supply and/or administer under a PGD will be taken voluntarily by the organisation dependent on clinical/business need. It is expected that before implementing a PGD the organisation will undertake an assessment of the capacity of the PT to take on extra responsibilities and ensure appropriate indemnity before they supply and/or administer a medicine or medicinal product via a PGD. Furthermore, any activities displaced are more likely than average to be those of the least value currently undertaken by PTs.

Benefits

Improved Efficiency and Cost Effectiveness

32. Allowing PTs to supply and/or administer medicines under a PGD may allow pharmacies to displace activities currently undertaken by pharmacists, freeing their capacity by maximising appropriate use of all professionals in the team. We assume the unit cash saving per hour of delegated activities is £55.00. This is the calculated utilising Band 6 PSSRU Unit Costs which include both wage and oncosts.[10]Considering the societal value of QALYs detailed earlier and assuming all benefits are realised by NHS providers, the social benefit equates to £256.67 per hour of delegated activities.

33. The extent to which activities are delegated to PTs is uncertain and will vary depending on the specific PGD and the proportion of the profession who undertake additional PGD training. This reflects current PGD use by pharmacists which varies significantly across different pharmacies.

34. Given this, we have assessed a range of scenarios consistent with those detailed earlier (and restated here), varying the estimated time currently spent by pharmacists supplying and/or administering medicines using PGDs as well as the proportion of this time which could be delegated to PTs. We vary the proportion of time currently spent by pharmacists using PGDs from 25% - 50% of hours worked, although uncertain, this equates to 409 – 818 hours per year per pharmacist. We assume between 25% - 50% of these activities may be delegated to trained PTs, resulting in 102 – 409 hours spent per year per PT using PGDs. We acknowledge this is highly uncertain and will vary significantly across pharmacies. The reality is that the time involved will vary with each individual case.

35. Combining these assumptions with our earlier assumptions for training the profession, the total undiscounted social benefit of delegating activities to PTs over 10 years is estimated between £1.1bn - £17.9bn. Discounting benefits at 1.5% results in a discounted social benefit over 10 years between £1.0bn - £16.3bn.

36. This estimate is highly uncertain. We have assumed PGD training allows PTs to undertake the same activities previously done by other healthcare professionals in the same amount of time. In reality, PTs may take longer, and this may vary depending on the specific PGD introduced.

Additional Benefits

[10] Personal Social Services Research Unit Costs of Health and Social Care 2022 (https://www.pssru.ac.uk/unitcostsreport/). Page 60.

37. For benefits to arise PTs must be trained to use PGDs and specific PGDs must be issued. There are numerous scenarios in which the use of PGDs may result in benefits. However, the scope for benefits will depend on the overall demand for PGDs and their specific circumstances. The consultation provided some qualitative comments about where benefits might arise (see below para 39 onwards) but has not identified any precise estimates of volume or a quantified estimate of clinical impact.

38. As such, although possible benefits of the policy change have been identified, it is not possible to fully quantify those impacts, and in particular the expected benefits to patients. To mitigate this, we have chosen to demonstrate a non-comprehensive range of potential indicative scenarios in which benefits may occur. We also consider any potential risks to patients, and associated mitigation.

39. Although not a policy change as such (PGDs are still used, just by different staff) it is worth noting that the service will be reimbursed for providing services under PGDs. Some of the costs of training pharmacy technicians to use PGDs may be offset by the increased capacity that the reforms could create. Additionally, Community Pharmacy in England will collect an NHS prescription charge where a medicine is supplied under a PGD and the patient is not exempt from paying a charge or has a prescription pre-payment certificate. Prescription charges do not apply elsewhere in the UK.

Scenarios where benefits may arise

PTs Administering Vaccinations

40. Community pharmacies have played an important role in the Covid-19 and flu-vaccination programmes. The experience, skills and knowledge of PTs has contributed to the vaccination programme from receipt, stock management and distribution of the vaccine, to support for preparation of the vaccine prior to administration.

41. The current legal and governance framework for vaccines does not allow PTs to administer vaccines where vaccination centres choose to operate their vaccination programme under a PGD. PTs have been able to administer vaccines where the choice of legal mechanism to support service has been PSD or National Protocol.

42. There is working experience and evidence of successful implementation of PTs skills across all parts of the patient's vaccination journey. The current model does not allow PTs to fully participate as the legal framework excludes them from certain parts of the process (e.g., patient consent). This leads to fragmentation in service provision that could be addressed using a PGD that allows PTs who complete specific PGD training, and are deemed competent, to be involved in the whole process.

43. Enabling PTs to administer vaccinations under a PGD could create more capacity for flu or COVID vaccination in community pharmacy and could free up pharmacists' time to deliver other clinical services. This will maximise the use of all healthcare professionals, improving efficiency and improve patient's experience by reducing delays.

Emergency Contraception

44. PTs in community pharmacy could supply Emergency Contraception (EC) in certain situations. Along with EC PGD competency training, PTs may have developed sufficient underpinning knowledge in human physiology, pharmacology of medicines and patient consultation skills, to provide a sound basis to enable appropriate assessment of the

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

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

PTs in Pre-Op Clinic

46. The PTs role in pre-op clinic includes medicines reconciliation, medication supply, patient counselling and discharge facilitation, often in patients categorised as 'low risk' on specific elective pathways. Working as part of the MDT to complete the patient assessment prior to surgery; medication history is taken and confirmed; inpatient prescription charts are transcribed ready for inpatient stay; advice and information is provided about medication both pre-op and post op, including what to stop and start, to minimise risks and optimise outcomes.

47. In all circumstances the PT can refer to a pharmacist or clinician. This allows Pre-Op clinical pharmacists to target their resources towards the management of more complex and/or high-risk patients, and for nursing time to be released for other duties/roles in the pre-op clinic. To further maximise skill mix and resource in the MDT and to enhance patient safety and experience, PTs, who complete specific PGD training and are deemed competent, could supply patients with; pre-operative bowel cleansing preparations (prior to colorectal surgery); medication for pre-op MRSA decolonisation and supply of pre-packed post-op analgesia consistent with certain procedure protocols.

48. The PTs underpinning knowledge, skills and competency support their role in assessing patient suitability and eligibility (including interpretation of patient results and medication history), consent, providing verbal and written advice and information to ensure appropriate administration by the patient, documentation in patient's record and referral to clinicians where appropriate.

Risks

49. This section considers the main risks related to the policy itself. Any risks with the analysis of impact, such as limited evidence and uncertainty are covered in the proportionality of analysis section above.

50. There are potential risks with extending medicines mechanisms to further regulated healthcare professionals. Most are not unique to PTs; they are the same as any proposal to allow a health professional to use PGDs to supply and/or administer medicines.

51. If PTs are authorised to supply and/or administer medicines to patients through PGDs, there is the potential that they may mistakenly supply and/or administer a medicine that is unsuitable for the patient. If this becomes more likely than in current practice, there will be an associated net health cost. The frequency of current errors is uncertain with their associated costs unknown as not all errors result in health costs.

52. Linked to this is the importance of ensuring all staff involved in the process are given proper training, advice and protection, to minimise the chance of error and the

consequences should errors occur. Without such protections, it is likely that some clinicians may be deterred from applying the new flexibilities. Mitigations include:

a. A PGD is a set of instructions which directs the healthcare professional in their assessment of the patient. Working through the protocol produces a clear indication of whether the patient should or should not have the medicine concerned. There is no scope for individual clinical decision making within a PGD. This reflects the level of education and training by the professionals who use them.

b. PGDs are developed by multidisciplinary groups with extensive expertise. They take a significant amount of time and resource to develop and implement and once implemented are subject to ongoing monitoring. This ensures that the indication whether to supply and/or administer the medicine given by the PGD is safe and appropriate for the defined patient group.

c. The National Institute of Clinical Excellence (NICE) has developed a medicines practice guideline on the writing, authorising, implementation and use of PGDs. They also provide a suite of tools for organisations, services and individuals to structure training and governance, and a set of standards against which organisations can monitor their performance. This guidance applies to England and Wales, however, the principles may be applicable in Scotland (and potentially in future, Northern Ireland). NHS England may also elect to complement this guidance with further advice.

d. The use of PGDs is expected to improve the quality of supply and administration. Currently, when delivering patient care PTs often need to request an independent prescriber to prescribe medicines or seek the help of another healthcare professional. The proposed use of PGDs would enable PTs to take responsibility for their decisions to administer and supply medicines in accordance with the written PGD introducing clearer lines of clinical responsibility and accountability.

53. PTs may supply and/or administer a medicine using a PGD without having undertaken either nationally available (CPPE) or locally provided training to use PGDs resulting in an increased risk of error. This risk will be mitigated by:

    a. Individual PTs must be signed off as competent to use each specific PGD, meeting educational and governance requirements specific to that PGD. Organisations should ensure that PTs have undertaken relevant training prior to using PGDs.

    b. PTs are required to only supply and/or administer medicines within their scope of practice and competence and the GPhC has the powers to invoke fitness to practice proceedings with potential removal of individuals from their register if the person falls below the standards required.

54. The limitations of the PGD mechanism may mean that not all the patients that PTs see will benefit from the proposed changes to legislation, such as those requiring medicines with variable dosing.

    a. Although there are some limitations to the PGD mechanism, scoping has identified that PGDs are the best fit for the profession currently.

55. The time taken for development, approval and review of PGDs can be lengthy which may delay the benefits for patients. This is not specific to PTs.

    a. Exemplar PGDs could be shared on the PGD website, hosted by the Specialist Pharmacy Service which could be accessed across the UK.

56. If the legislation is not amended to enable PTs to supply and/or administer the controlled drugs that most other professions can using PGDs, this could lead to confusion within organisations, inconsistency for patients seeing different health professionals who are providing the same type of care, and increased risk of error.

    a. Information could be provided on the Specialist Pharmacy Service website and the training package updated to make the position clear.
    b. Separate profession-specific PGDs would need to be written for services where the same type of care is provided to patients by PTs and other professions who can supply and/or administer controlled drugs.

57. Increasing the responsibilities of PTs may place increasing pressure on the wages of PTs going forward.

    a. Impacts on wages resulting from the proposal would represent an economic transfer of the private benefits accruing to pharmacies transferring to PTs.

Equality/ Distributional impacts

58. Patients who are provided care by PTs could receive the treatment they need without additional appointments or delays to visit a more senior prescriber. A reduction in delays and the time taken to access health care professionals, which by their nature are variable, may make treatment more consistent between patients in similar situations. That will improve equality of treatment and potentially lead to less variation in clinical outcomes. Although not possible to measure the precise impact of this reform on disparities, poor health is strongly correlated with both deprivation and age, such that patient benefits may be disproportionately achieved by those at the disadvantaged end of the spectrum.

59. PGDs provide a structured framework which permits certain healthcare professionals to supply and/or administer medicines to a pre-defined group of patients. Any patient that falls outside the pre-defined group cannot be treated under that PGD and must be referred to an independent prescriber for more thorough assessment. This could mean that this mechanism for obtaining medicines will be less available for those with pre-existing medical conditions (slightly offsetting the disproportionate benefits mentioned above). However, increasing the accessibility of medicines for those within the defined patient group could help to free capacity for appointments within other parts of the healthcare system.

60. In terms of regional impacts, the reform will apply to Great Britain only. Pharmacy technicians in Northern Ireland are not a registered healthcare profession so amendments to the Human Medicine Regulations 2012 (HMRs) cannot currently allow pharmacy technicians in Northern Ireland to use Patient Group Directions. However, should pharmacy technicians in Northern Ireland become a registered healthcare profession, a further amendment to the HMRs may be made to permit this.

Proposed implementation plan of preferred option

61. Once the regulation comes into force, registered pharmacy technicians, where appropriately trained and competent, will be able to utilise Patient Group Directions. It will be up to individual pharmacy teams to identify how best to use the reform to add value to their service provision. NHS England may wish to promote the reforms and issue guidance using its regular communication channels, for example the Primary Care Bulletin.

62. Commissioning PGDs for use by PTs would be optional, to be determined at a local level depending on patient need and service requirements. It is not guaranteed that every registered pharmacy technician will become PGD-trained.

Private sector impact (including Small & Micro Business Assessment)

63. Many pharmacy services are in the private sector, or have privately employed staff, even when contracted to provide NHS services. There remains no obligation for private organisations or individuals to undertake PGD training. This will remain voluntary and is at the discretion of local organisations. As such, the impact of the proposed change on private businesses is expected to follow the same profile as the main analysis of costs and benefits above.

64. Impacts are expected to fall in direct proportion to the number of occasions where PGDs are conducted by PTs in future, and to a lesser extent in line with the number of affected staff. In practice that means that larger organisations (in terms of PGD use) will see greater potential for both training and subsequent benefits.

65. Small businesses are more likely to appear in primary care, where the community pharmacy sector in England consists of 10,519 active community pharmacies (as of March 2024).[11] Of these, we estimate that around 4,800 will be in small firms (1-5 branches, or less than 50 employees). The remainder form part of larger chains.

66. There are some 6,500 pharmacy technicians employed in community pharmacy.[12] On a pro-rata basis, small firms may have relatively small numbers of PTs, of which only a proportion might be eligible to take up the new training offer. Many community pharmacies will not employ PTs at all and thus not be directly affected by these reforms. It remains true that businesses would only take advantage of the new rules if they felt it was beneficial to do so, so although the impacts might be small proportionately, smaller firms would still benefit to the extent that their staffing levels permit the additional flexibility to be used.

67. In terms of the specific costs and benefits, there is little difference between smaller firms and other affected organisations in terms of what and when impacts arise. The training costs are fixed (3 hours per person) so there may be some economies of scale for larger firms dealing with more PGDs. Any pressure on wages may be more difficult for a smaller firm to bear, but even in that situation, the benefits would be expected to outweigh the cost, assuming the decision to train staff (or employ highly trained) reflected business need. It is acknowledged that the realities of recruitment, staff shortages and other practicalities may prevent optimal efficiency.

68. In summary, any impacts on businesses are expected to be voluntary. Small firms will predominantly arise in community pharmacy and will be able to take advantage of the new flexibilities commensurate with their use of PGDs and employment of PTs. Larger firms may achieve economies of scale (as they would in many aspects of business) but all firms will have the potential to benefit. The net financial benefit to business of improved efficiency is dependent on the private sector's ability to convert efficiency savings into income.

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[11] NHSBSA Pharmacy Openings and Closures - March 2024. Pharmacy Openings and Closures - PHARMACY_OPENCLOSE_202403 - Open Data Portal BETA (nhsbsa.net)

[12] NHS Health Education England. Community Pharmacy Workforce Survey 2021. https://www.hee.nhs.uk/sites/default/files/documents/The%20Community%20Pharmacy%20Workforce%20in%20England%202021%20-%20Survey%20report_0.pdf

69. The assumption and expectation that there will be no significant change in treatment (instead just improved access for patients to receive their medicines) means that the impact on the supply chain, manufacturers and so on is likely to be negligible.

70. In general, health improvements can reduce sickness absenteeism for employers, although the impact here is likely to be negligible (notwithstanding the potential for fewer pharmacy visits or appointments to be needed).

Evaluation and Monitoring

71. This impact assessment draws on a range of evidence, including bespoke feedback from the consultation exercise. Nevertheless, quantified estimates of uptake and impact remain uncertain. Any consequences arising from this risk will be mitigated through regular engagement with the sector. The Department has no separate plans to formally evaluate the policy because local monitoring of the changes will be undertaken where the PGDs will be used.

Operational monitoring

72. As explained in the consultation, the governance involved in developing a PGD ensures there is clear accountability, delegation, monitoring and a structured work programme for reviewing, updating and re-authorising PGDs.

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

74. There should be ongoing monitoring and assurance of the use of the PGD undertaken by the commissioner. All registered pharmacy technicians are regulated by the General Pharmaceutical Council (GPhC). Therefore, there will be monitoring at a local level carried out by the local commissioner, in addition to regulatory scrutiny provided by GPhC.

75. Under existing legislation all registered pharmacy technicians are regulated and accountable to the GPhC.

Legal monitoring

76. Section 46 of the Medicines and Medical Devices Act 2021 (MMDA) requires the Secretary of State to lay a report before Parliament every two years on the operation of regulations made under section 2(1) (and other powers under the Act) with the next reporting period concluding in July 2025. Consequently, the instrument does not include a bespoke statutory review clause. In line with the requirements of the Small Business, Enterprise and Employment Act 2015, Minister Andrea Leadsom has made the following statement:

"It is not appropriate in the circumstances to make provision for review in this instrument. This is because there is already a requirement in section 46 of the Medicines and Medical Devices Act 2021 to review the operation of these Regulations every 24 months".

74. The above operational and legal monitoring steps will take immediate effect and be used to both ensure that the reform is having the desired effect, and that any learning points or improvements are identified and acted upon.