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** **RPC Reference No:** **Lead department or agency:** Dept. of Health & Social Care **Other departments or agencies:** NHS England, Medicines and Healthcare products Regulatory Agency	**Impact Assessment (IA)** **Date:** July 2023 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:**

Summary: Intervention and Options

RPC Opinion: n/a

Cost of Preferred (or more likely) Option (in 2019 prices)			
Total Net Present Social Value £m	**Business Net Present Value** £m	**Net cost to business per year** £m	**Business Impact Target Status** Qualifying provision

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

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 the NHS systems across all four nations of the UK, 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/will not be reviewed. **If applicable, set review date:** Month/Year

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:**	**Non-traded:**	

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

Signed by the responsible Minister: Date: 25 July 2023

Summary: Analysis & Evidence

Policy Option 0 – Do Nothing

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2020	Time Period Years 10 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				**0**
High				**0**
Best Estimate				**0**

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

Patient choice and access to medicines will remain at current levels, with no improvements made to patient health outcomes. Workforce capacity will not be improved with the skill mix of pharmacy teams remaining at current levels.

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

None

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

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

None

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

None

Key assumptions/sensitivities/risks	Discount rate (%)
This is the status quo option. By continuation, the associated costs and benefits are set to 0. Costs and benefits of other options are expressed relative to this option.	

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:**	

Summary: Analysis & Evidence Policy Option 1 – Proposed Change

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2023	Time Period Years 10 Years	Net Benefit (Present Value (PV)) (£m)		
			Low: £331.2mn	**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			**£690.0mn**
High			**£11.0bn**
Best Estimate			**£3.9bn**

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

PTs require training to use PGDs which results in opportunity costs. As training is voluntary, we vary the proportion of the profession who may uptake training from 25%-100% to provide sensitivity. This cost will be borne by local organisations employing PTs.

Expanding the role of PTs may pressure their existing roles and responsibilities, suggesting an associated opportunity cost which could be borne by local organisations employing PTs. The amount of time spent by PTs undertaking additional activities is uncertain and 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. Our best estimate of costs is derived utilising the median of our variable ranges, resulting in a downwards bias due to the multiplicative nature of variables used within our assumptions.

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

Administrative costs associated with developing and reviewing PGDs. These costs may vary significantly depending on the complexity of PGDs and as such will be monetised following further consultation. PGDs are developed locally by organisations that require their staff to use PGDs to provide a service and therefore, these costs will 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. Our best estimate of costs is derived utilising the median of our variable ranges, resulting in a downwards bias due to the multiplicative nature of variables used within our assumptions.

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 depend on the demand for PGDs and the specific PGDs introduced, both of which we are aiming to clarify via further consultation with stakeholders.

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:	

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 34-42.

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 the NHS systems across all four nations of the UK, 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.

Policy objective

5. The aim of this policy is to include PTs in the list of registered health professionals able to supply and/or administer medicines under PGDs. This policy contributes to the ambitions of the NHS systems across all four nations of the UK, to further integrate community pharmacy into the NHS and maximise the use of skill mix in pharmacy teams, enabling them to meet more of the health needs of their local populations.

6. Enabling PTs to use their skills and knowledge to undertake more clinical services via a PGD may 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.

7. Enabling PTs to use PGDs may 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.

8. 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)

9. There is limited data available on the possible impacts of this policy change. As such, we are aiming to gather further insights from consulting with stakeholders on the proposed change. This includes, but is not limited to, gathering estimates of potential time savings that could result from the use of PGDs within pharmacy teams. Additionally, we are aiming to refine our estimates of the scale/demand for the introduction of PGDs and the demand to train PTs to use PGDs.

10. Given data limitations we have used a range of indicative scenarios to demonstrate potential situations where the policy change may be expected to provide benefits.

11. The Association of Pharmacy Technicians UK, Royal Pharmaceutical Society and Company Chemists Association have been broadly supportive of the policy. Policy officials from each Devolved Administration (DA) have been informed of the department's proposal to consult as well as the CPhOs representing each DA.

Description of options considered

Option 0 – No Change

12. 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 – Adding Pharmacy Technicians to the list of registered health professionals able to supply and/or administer medicines under PGDs.

13. 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 utilise the skill mix in pharmacy teams. 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.

14. The proposed change would 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.

15. 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

16. In line with NICE Guidance, additional on-line training (most likely using the eLfH programme available from the Specialist Pharmacy Service) will be required for PTs to understand the mechanism to use PGDs. This training is free to access and is estimated to take approximately 3 hours. 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[1] which includes both wages, oncosts and overheads).

17. Department of Health and Social Care (DHSC) estimates the cost at which QALYs are gained at the margin is £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 x 4.7 x 3 hours). This cost will be borne by local organisations employing PTs.

18. 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 appraisal period). Assuming of those who demand 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% results in a discounted training cost over 10 years between £3.0m - £11.9m.

19. This estimate is highly uncertain and is likely an underestimate. No growth has been applied to the profession over time. Additionally, training time may exceed 3 hours as there is no time limit and potential compliance costs of training have been assumed to be negligible. Additional training may also be required according to the training and education requirements included in a specific PGD. We aim to refine our estimates of the demand for training via consultation.

PGD Costs

20. There will be an additional cost resulting from developing and authorising PGDs for PTs. The time to develop and review PGDs may vary significantly depending on the PGDs content and complexity. Given the significant uncertainty, with possible timings ranging from days to weeks, we are looking to gather further stakeholder input via consultation. As such, this cost is currently not monetised. However, reviews of PGDs, and their associated costs, are expected to occur at least every 3 years following NICE guidelines.

21. This cost will be scaled by the expected demand for PGDs which will be informed by further discussions with stakeholders.

Existing PT Responsibilities

22. Expanding the role of PTs may pressure 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. This suggests there will be an opportunity cost associated with the displacement of current PT activities.

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

23. 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 (£37.00 x 4.7), following the methodology detailed in paragraph 17. 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.

24. 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. As such, we will gather further evidence from consulting with stakeholders.

25. Combining these assumptions with our assumptions for training the profession detailed in paragraph 18, 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.

26. This estimate is highly uncertain and is likely an overestimate. 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 likely to be those of the least value currently undertaken by PTs, suggesting the use of Band 4 PSSRU Unit Costs may overestimate the value of any activities lost.

Benefits

Improved Efficiency and Cost Effectiveness

27. Allowing PTs to supply and/or administer medicines under a PGD may 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. Considering the societal value of QALYs detailed in paragraph 17 and assuming all benefits are realised by NHS providers, the social benefit equates to £256.67 per hour of delegated activities.

28. 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.

29. Given this, we have assessed a range of scenarios consistent with those detailed in paragraph 24 (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. As such, we will gather further evidence from consulting with stakeholders.

30. Combining these assumptions with our assumptions for training the profession detailed in paragraph 18, 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.

31. 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. Give this uncertainty, we aim to refine our estimates via further stakeholder discussions.

Additional Benefits

32. 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 benefits arising from the use of PGDs will depend on the overall demand for PGDs and the specific PGD considered. As such, we are aiming to consult stakeholders on the expected demand for PGDs and the benefits they estimate will arise in such circumstances.

33. Although possible benefits of the policy change have been identified, we are unable to fully quantify impacts prior to consultation, such as the expected benefits to patients. There is little available information analysing the impacts of the policy change given its specificity. We recognise further consultation is required to build the necessary evidence base to fully analyse this policy change. As such, we have chosen to demonstrate a non-comprehensive range of potential indicative scenarios in which benefits may occur.

Scenarios where benefits may arise

PTs Administering Vaccinations

34. 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.

35. 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.

36. 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.

37. 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

38. PTs in community pharmacy could supply Emergency Contraception (EC). Along with EC PGD competency training, the underpinning knowledge gained in human physiology, pharmacology of medicines and patient consultation skills, provides a sound basis to enable appropriate assessment of the presenting patient in terms of suitability and eligibility for a supply (inclusion criteria, concomitant medication and medicines interactions); consent; ability to signpost patients to appropriate services should they not be eligible; advice in relation to administration, side effects and risks should the patient decline treatment after counselling.

39. 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

40. 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.

41. 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.

42. 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

43. 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. Possible risks have been listed alongside bulleted lists of mitigating actions.

44. If PTs are able to supply and/or administer medicines to patients through PGDs, there is the potential that they will 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. Following consultation, and the further quantification of the proposal, we intend to conduct a break-even analysis to assess the sensitivity of the proposal to possible changes in error rates.

    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 Northern Ireland.

    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.

45. 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.

    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.

46. 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.

47. 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.

    b. Given the significant uncertainty over timings we hope to gather stakeholder input via consultation.

48. 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.

49. 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

50. 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. 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.

Proposed implementation plan of preferred option

51. Input from the consultation, alongside further stakeholder discussions, will be used to help determine the suitability of the proposed change. Commissioning PGDs for use by PTs would be optional, to be determined at a local level depending on patient need and service requirements.

Private sector impact

52. There is no obligation for private organisations or individuals to undertake PGD training. This will remain voluntary and is at the discretion of organisations.

Evaluation and Monitoring

53. Following consultation of the proposed change we will discuss appropriate evaluation and monitoring plans, considering the relevant NICE guidelines where appropriate.