



The Pharmacists' Defence Association's response to the Department of Health and Social Care Consultation: "Proposal for the use of patient group directions by pharmacy technicians."

September 2023

Summary

This consultation by the Department of Health and Social Care (DHSC) is seeking views on the proposal to enable registered pharmacy technicians to supply and administer medicines under a patient group direction (PGD).

The consultation document states that the proposal is supported by all four nations across the UK, and it links to several documents where it says the future ambitions for the pharmacy technician profession are detailed.

However, many of these documents are not Government or DHSC documents but are merely papers produced by other organisations.

The consultation states that the required legislative changes will be implemented by a statutory instrument (SI) under enabling powers in the Medicines and Medical Devices Act 2021 (MMD Act).

The proposed changes would enable registered pharmacy technicians to use PGDs across England, Wales and Scotland in any setting including the NHS, independent and voluntary sectors.

In light of the 150 word constraint imposed on the online consultation form the PDA has sent this more detailed response to the DHSC for consideration.

Response to Questions.

Do you agree or disagree with the proposal to amend the Human Medicines Regulations (2012) to enable pharmacy technicians to supply and administer medicines to patients using PGDs?

Agree

Disagree ✓

Don't know

If you have any additional information to support your answer, please provide details (maximum 150 words).

In our online submission which was limited to 150 words we abbreviated pharmacy technician to PT due to the word count restriction.

The PDA supports appropriate skill-mix and pharmacy technicians (PTs) undertaking activities appropriate to their underlying education.

However, on patient safety grounds we strongly disagree with this proposal because:

- ***It will lead towards role substitution – pharmacists being substituted by PTs.***
- ***PTs fail to satisfy the NICE competency framework for healthworkers using PGDs.***
- ***The underpinning education of a PT Level 3 qualification is inadequate.***
- ***There is variance in quality and delivery of accredited PT courses leading to registration.***
- ***There is no central registration assessment to maintain consistency of standards for entrance onto the register (unlike for pharmacists).***
- ***The 2 year education and training of a PT (IETPT) requires only 14 hours work experience per week.***
- ***50% of the current PT workforce entered the register via a grandparent rule. The chair of pharmacy regulator in 2014 acknowledged the impact of this incomplete educational record leading to the very variable standard of the PT register.***

The PDA has listed some of our major concerns in the 150-word summary. These together with others which are not listed due to word space limitations are discussed in this emailed response.

The consultation document states that the proposal is supported by all four nations of the UK and links to several documents to support this assertion. The Welsh 2030 Vision clearly sees:

“Pharmacists and pharmacy technicians have complementary roles in improving medicines related outcomes for patients.

Pharmacists will be primarily focused on the clinical and therapeutic interventions, whilst pharmacy technicians improve medicines outcomes with practical advice on the use and management of medicines.”¹

The Scottish 2030 document, created in partnership with the National Pharmacy Technician Group Scotland clearly sees:

“The main role of pharmacy technicians will be to lead medicines management processes to ensure patients receive a safe and effective supply of medicines.”²

The pharmacy technician roles described in both documents outline technical roles in line with, and suitable for, the level 3 qualification. Supply or administration of a medicine using a PGD involves **using and applying** complex consultation and clinical skills which are outside the training scope of the level 3 IETPT. The decision to supply or administer an item using a PGD should only be made following a detailed consultation with the patient. We discuss this more in later sections.

It is important to highlight at this juncture that every part of the PGD process, from start to finish, should be undertaken by only one individual. If a pharmacy technician was allowed to undertake a PGD it would not be a case that this would occur under the supervision of a pharmacist, nor can it be that a pharmacist could undertake one part (for example the consultation to determine consent or taking clinical history) and the pharmacy technician another part (for example administering the vaccination or making the supply).

The PDA supports appropriate skill-mix within all pharmacy settings and recognises the important contribution that all members of these teams play in safely delivering healthcare to their patients.

However, this proposal to allow pharmacy technicians to work under PGDs is not about skill-mix. This is essentially about role substitution and involves pharmacists (seen as being costly) being substituted by pharmacy technicians (employed at substantially cheaper rates). National earnings data³ for 2022 showed that the median hourly pay for a pharmacist at £23.56 and for a pharmacy technician at £12.93. There may be a significant financial aspect which may be a driver for allowing pharmacy technicians to undertake work under a PGD.

This became clear at the webinar hosted by NHS England on the 7th of September 2023 where it was emphasised by “senior” pharmacy technicians that the remuneration received by a community pharmacy would be the same irrespective of whether it was the pharmacist or the pharmacy technician that supplied or administered the medicine specified in the PGD. The focus seems to be on substituting a level 7 educated pharmacist with an inappropriately qualified pharmacy technician to deliver a service, but which still costs the NHS the same amount of money.

Thus, if this proposal goes ahead the NHS will be paying the same price for a specified service but the service would be delivered by a level 3 educated healthcare worker that is much cheaper to employ than a level 7 educated healthcare professional. The main financial beneficiary will be the owner of the business that receives the payment from the NHS.

Even more worrying is the statement made in the Impact Assessment for this proposal:

“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.”⁴

It is worrying that the DHSC proposal openly states that it will not be patient safety that would determine whether a pharmacy technician would use a PGD, nor would it be the Responsible Pharmacist – the person with statutory responsibility for the safe and effective operation of the pharmacy and also the person in the best position to make an assessment on the ability of a pharmacy technician but it would be a “business decision” dependent upon “business need”.

Understanding the basis of a Patient Group Direction

The National Institute for Health and Care Excellence in its PGD Guideline ⁵ says a PGD comprises:

‘Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment’

This cohort of patients, who are **not** individually identified, **may** be eligible to receive the supply or administration of the medicine specified in the PGD. The health worker authorised in the PGD is responsible for determining that eligibility and for ensuring that the supply or administration of the medicine is appropriate for that **individual patient**.

41. When practising under a PGD, health professionals should:

- not [delegate](#) their responsibility
- ensure that they can determine that the patient meets the inclusion criteria as set out in the PGD
- ensure that they can determine that no exclusion criteria apply
- discuss alternative options for treating the patient's condition, when appropriate
- assess each individual patient's circumstances and preferences
- recognise when signposting or referral to another health professional or service is needed, as specified in the PGD
- understand relevant information about the medicine(s) included in the PGD, such as:
 - how to administer the medicine
 - how the medicine acts within the body
 - dosage calculations
 - potential adverse effects and how to manage them
 - drug interactions, precautions and contraindications
 - storage requirements, including maintenance of the 'cold chain'
 - follow-up arrangements
- be able to advise the patient or their carer about the medicine(s), as appropriate.

Delegation

Supply and/or administration of a medicine must not be assigned or delegated to any other person under a PGD, regardless of their professional group or level of training. For example, if the medicine is to be administered under a PGD, such as influenza vaccination, this should be by the same health professional that assessed the patient under the PGD.

The health worker must make a clinical decision, based on several factors, whether the presenting individual can be safely supplied or administered the medicine.

The health worker cannot delegate (or escalate) this decision-making process which must be undertaken for every individual patient.

The Association of Pharmacy Technicians UK (APTUK) in a position statement dated 15th May 2018 stated:

Lack of underpinning knowledge resulting in a detrimental impact on patient safety - If the PGD routinely required a level of underpinning knowledge beyond that of a pharmacy technician, then it would not be appropriate for a pharmacy technician to deliver this service. This would/should be picked up during the risk assessment in the PGD development stage.

Any infrequent need for underpinning knowledge can safely be managed by referring back to a pharmacist when required. A systematic approach to service delivery using referral and handover tools can produce decision points to allow appropriate escalation.⁶

This is the level of misunderstanding that exists within APTUK which describes itself as the professional leadership body for pharmacy technicians. The position of APTUK does not acknowledge that a PGD should **never** require a level of underpinning knowledge beyond the scope of any group of healthcare workers that are authorised within the PGD.

It is perfectly understandable that APTUK would like the option to refer back to a pharmacist, but this is in effect “delegating” that responsibility back to a pharmacist and thus defeats the purpose of including pharmacy technicians within the scope of PGDs.

The NICE guideline above acknowledges that there may be occasions when it is necessary to “*recognise when signposting or referral to another health professional or service is needed, as specified in the PGD*”.

However, this would occur because of the person using the PGD to supply or administer the medicine having the underpinning scientific and clinical knowledge to recognise and understand that a referral is needed. The signposting provision is not there to cover for a lack of underpinning knowledge.

The Pharmacy Technician Register – The Grandparenting Issue

Around 50% of the current pharmacy technician workforce in Great Britain have entered the General Pharmaceutical Council (GPhC) register through a grandparenting arrangement.

The impact of this was clearly understood by the incoming chair of the GPhC when asked, at the Royal Pharmaceutical Conference in 2014, why the GPhC had thus far failed to provide a statement which clarified that pharmacists should be able to confidently delegate tasks to registered pharmacy technicians.

In response he stated that there were some very variable standards amongst those on the register. He explained that it was therefore not possible for the regulator to take a blanket view and to recommend to pharmacists what roles they should delegate to pharmacy technicians. A generic approach to the group was not possible.⁷

In 2014 around 80% of the pharmacy technicians register comprised of those that had entered through the grandparenting arrangement.

The issue with PGDs is not specifically about delegation, but when even delegation under the supervision of a pharmacist may not be appropriate for many pharmacy technicians on the register, how can a blanket proposal to allow pharmacy technicians to work under PGDs be deemed to be safe or appropriate?

The proposals to allow pharmacy technicians to work under PGDs is a blanket approach – the very approach which the GPhC has justifiably steered away from.

The issue around the impact of the grandparent route onto the pharmacy technician register is discussed more fully in the PDA 2019 technician report.⁷

As the regulatory responsibility was passed from the RPSGB to the GPhC in 2011, the specific list of qualifications and experiences that were held by the pharmacy technicians entitling them to enjoy the grandparenting was lost.

The GPhC did not receive any specifications – just a list of names; the PDA is not aware that this situation was subsequently repaired. The incomplete educational record of 50% of the **current** pharmacy technician register is not the only issue. The current Initial Education and Training of Pharmacy Technicians (IETPT) is also problematic, and we discuss this further in the next question.

The issue of a profession and the blurring between roles.

Where roles in healthcare settings blur, patient safety issues are created. This is not unique to pharmacy. The recent concerns expressed by the BMA around the role of Physician Associates is another example.

There is a substantial discussion about the role of pharmacy technicians in the 2019 PDA Pharmacy Technicians report. We strongly advocate that this response be read with the fully referenced discussion in that report.

Some individuals and organisations have repeatedly promoted the use of the term “Pharmacy Professionals” over recent years. This wording attempts to merge the populations of pharmacists and of pharmacy technicians into one, and it is a concern that it appears some people are now incorrectly thinking of the two roles as a homogenous group. This proposal to enable pharmacy technicians to use PGDs illustrates why the PDA has consistently challenged the use of the term “pharmacy professionals”.

The PDA represents pharmacists, and our members feedback repeatedly acknowledges the value and contribution of pharmacy technicians. Our members recognise that pharmacies operate safely when all members of the team work together within the limits and boundaries of each individual’s underpinning clinical knowledge.

Do you agree or disagree that the 2-year pre-registration training equips pharmacy technicians with the appropriate knowledge and skills to complete the training requirements which allow them to use PGDs?

Agree

Disagree ✓

Don’t know

If you have any additional information to support your answer, please provide details (maximum 150 words).

In our online submission which was limited to 150 words we stated:

The IETPT delivers a Level 3 occupational qualification and the learning outcomes do not equip pharmacy technicians with the requisite level of underpinning knowledge and skills to safely supply or administer medicines under PGDs.

For example, the IETPT requires only a basic level of understanding of pharmacological principles to the use of medicines in relation to disease processes and the treatment of identified clinical conditions. Similarly, the IETPT outcome requires only a basic understanding of principles of biology, microbiology, physiology, and chemistry.

PGDs require autonomous working and decision making within a framework. However, such a framework is based on a core level of underpinning education. Every group of healthcare workers currently allowed (15 categories) to work under a PGD has a minimum of a level 5 qualification. This difference may seem small, L3 vs L5 but the educational gap between these levels is huge.

Pharmacists in all settings usually work as part of a team and PDA members recognise and value the support of all their support staff including pharmacy technicians.

However, member feedback has always highlighted the variable quality of understanding of basic pharmacology and basic science which many pharmacy technicians demonstrate and which our members usually attribute to the inconsistent quality of the training pharmacy technicians are receiving and which one member described as **“a vast variation in the quality of training”**

Underpinning science and pharmacology

The IETPT is a level 3 qualification, entry to which requires 4 GCSEs or an existing level 2 pharmacy qualification. The plethora of Level 2 courses and the obscurity of the entry process for these is important to understand as many technicians will have completed such a level 2 course as their entry qualification to the level 3 pharmacy technician course. The GPhC webpage⁸ is extremely unhelpful and virtually incomprehensible to anyone except those whose only interest is in the education of pharmacy support staff in clearly identifying minimum entry criteria for the level 2 course. However, what we can be certain of is that there is no specific science requirement to commence the level 2 qualification.

The issue of the level 2 course is important as the entrance requirement is significantly weaker than for the level 3 course (which is in any case weak itself). In secondary care around 50% of pre-registration trainee pharmacy technician vacancies are filled by

pharmacy support staff.⁹ The recently published community pharmacy workforce data for England¹⁰ showed an even greater reliance on level 2 qualified staff training to be pharmacy technicians. The data shows 2,533 level 2 assistants who are training to be pharmacy technicians, compared to 793 training to be pharmacy technicians via the pre-registration pharmacy technician pathway.

The current Level 3 pharmacy technician course

Even the current pharmacy technicians Level 3 qualification is inadequate as a foundation which would allow pharmacy technicians to undertake PGDs. The current Initial Education and Training of Pharmacy Technician (IETPT) standards¹¹, which came into operation in 2017, expects only a basic and rudimentary level of knowledge of basic science and pharmacology at the end of the IETPT. We can map this against the learning outcome in the Initial Education and Training for Pharmacist (IETP) standards.¹²

IETP Learning Outcome	IETPT Learning Outcome
	Understand the basic principles of biology, microbiology, physiology and chemistry
Apply the principles of clinical therapeutics, pharmacology and genomics to make effective use of medicines for people, including in their prescribing practice	Understand the basic pharmacological principles that apply to the use of medicines in relation to disease processes and the treatment of identified clinical conditions
Apply the science behind pharmacy in all activities	

If we look at other learning outcomes, we can see that there is a fundamental deficiency in the IETPT (we have mapped them against the IETP to illustrate the deficiency).

Some sections are left blank as there is no equivalent (for example within the IETP the learning outcome for biology, chemistry etc will be to the MPharm level 7 standard)

IETP Learning Outcome	IETPT Learning Outcome
Obtain informed consent before providing care and pharmacy services	Apply the principles of information governance and ensure patient confidentiality
Demonstrate effective consultation skills, and in partnership with the person, decide the most appropriate course of action	Advise people on the safe and effective use of their medicines and devices
Take an all-inclusive approach to ensure the most appropriate course of action based on clinical, legal and professional considerations	

Consider the quality, safety and risks associated with medicines and products and take appropriate action when producing, supplying and prescribing them	Ensure the quality of ingredients to produce and supply safe and effective medicines and products
Appraise the evidence base and apply clinical reasoning and professional judgement to make safe and logical decisions which minimise risk and optimise outcomes for the person	Apply professional judgement in the best interests of people
Critically evaluate and use national guidelines and clinical evidence to support safe, rational and cost-effective procurement for the use, and prescribing of, medicines, devices and services	Understand how to work within the local, regional and national guidelines and policies
Anticipate and recognise adverse drug reactions, and recognise the need to apply the principles of pharmacovigilance	Recognise adverse drug reactions and interactions and respond appropriately

The clear expectation and underlying basis for pharmacy technicians only to have a basic understanding in fundamental science is because they are expected to work under the supervision of a pharmacist.

The **current** integrated pharmacy technician apprenticeship describes the course as equipping the trainee pharmacy technician to:

“Overview of the role | Assisting the pharmacist in chemists and hospital dispensaries.”¹³

The introductory occupation summary to this integrated pharmacy technician apprenticeship simply says of pharmacy technicians:

“They are able to work with minimum supervision, with a high degree of autonomy ..”

Minimum supervision is distinct from no supervision and working autonomously is distinct from working with a high degree of autonomy. Any healthcare worker undertaking a PGD must be able to work under the specification of the PGD without supervision and autonomously.

The following table lists the education level of all the healthcare occupations that are authorised to use PGDs. The underpinning education is substantially and significantly greater than the basic level 3 qualification of pharmacy technicians.

Qualified healthcare professional who can supply or administer under a PGD			
Current Professionals	Qualification	Educational Level*	Link
· chiropodists and podiatrists	University Degree: BSc or MSc (4y)	6 or 7	Podiatry Careers Podiatry Courses & Training - - Health Careers
· dental hygienists	University: Foundation degree or Diploma of higher education or BSc	5 or 6	Dental therapy and dental hygiene (gdc-uk.org)
· dental therapists	University: Foundation degree or Diploma of higher education or BSc	5 or 6	Dental therapy and dental hygiene (gdc-uk.org)
· dieticians	Undergraduate BSc or post-graduate Diploma	6 or 7	How to become a dietitian British Dietetic Association (BDA)
· midwives	University Degree: BSc or MSc (post-grad)	6 or 7	Course finder Health Careers
· nurses	University Degree: BSc or MSc (post-grad)	6 or 7	Course finder Health Careers
· occupational therapists	University Degree: BSc	6	Course Finder Health Careers
· optometrists	University Degree: BSc or MSc	6 or 7	Course Finder Health Careers
· orthoptists	University Degree: BSc or MSc (post-grad)	6 or 7	Course Finder Health Careers
· orthotists and prosthetists	University Degree: BSc or MSc (post-grad)	6 or 7	Course Finder Health Careers
· paramedics	University Degree: Bsc or MSc (4y)	6 or 7	Course Finder Health Careers
· pharmacists	University Degree: Master of Pharmacy	7	Course Funder Health Careers
· physiotherapists	University Degree: BSc or MSc (4y)	6 or 7	Course Finder Health Careers
· radiographers	University Degree: Bsc	6	Course Finder Health Careers
· speech and language therapists	University Degree: BSc or MSc (4y)	6 or 7	Course Finder Health Careers
Proposed addition			
· pharmacy technicians	Part time NVQ 2 years	3	Course Finder Health Careers

* [Qualification levels](#)

Do you agree or disagree that allowing pharmacy technicians to supply and/or administer under a PGD will enable safe access to medicines for patients?

Agree

Disagree ✓

Don't know

If you have any additional information to support your answer, please provide details (maximum 150 words).

In our online submission which was limited to 150 words we stated:

PGDs are designed for specific cohorts of patients and the criteria for administration or supply are tightly defined. NICE lists 9 requisite competencies within 3 domains for healthcare worker using PGDs. These are highly complex competencies underpinned by a level of education far exceeding the basic standard of the IEPTP.

To address the inadequacy of the Level 3 PT course in terms of clinical skills, level 4 courses are available. For example, the University of East Anglia offers a level 4 course with significant focus on clinical therapeutics.

To enable PTs to work safely under a PGD, a separate suite of PGDs will be needed for use only by them. These PT-specific PGDs will need to mandate robust, comprehensive additional training to ensure the standards specified by NICE are met, and to provide a means of recording whereby PTs can demonstrate to employers and RPs completion of the required training.

Why having an underpinning knowledge of science and pharmacology is important to assure the safe supply or administration of medicines.

The consultation and the impact assessment specifically note the role of PGDs in the supply of Emergency Contraception. The consultation document asserts:

Registered pharmacy technicians in community pharmacy are well positioned to 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*

We have already noted that to satisfy the IETPT course requirement a pharmacy technician will only have gained a **basic knowledge of the basic principles** of biology, microbiology, physiology and chemistry together with basic pharmacological principles that apply to the use of medicines in relation to disease processes and the treatment of identified clinical conditions.

Paragraph 38 in the Impact Assessment makes a similar statement to the one quoted above from the consultation. Paragraph 39 explains the basis on which a pharmacy technician would supply Emergency Contraception:

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.¹⁴

We can examine this by looking at a current PGD for use by a pharmacist in community pharmacy.¹⁵ Within this 23 page document there are complex issues around safeguarding, informed consent, off-label use and it is clear that it is already assumed that the pharmacist has underpinning clinical knowledge and understanding of a whole range of clinical issues such as hepatic impairment or enzyme inducing agents which may have an impact on the appropriateness of the supply and potentially the dose.

We accept that some of the training around the **non-clinical aspects** (for instance knowledge about local policies around safeguarding) can be learnt by a pharmacy technician.

However, it is the complex underpinning clinical, biological and pharmacological aspects that lie well outside the competency of pharmacy technicians. This cannot be reduced to a tick box or an algorithm with yes/no. A patient may present with multiple underlying issues and the individual and cumulative impact of the decision to supply or not, to vary the dose or not and the decision made by the healthcare professional may have profound implications (including psychological) for the patient.

Off label use

This PGD includes off-label use in the following conditions:

- o use between 72 and 96 hours post UPSI
- o consideration of increased dose for individuals with BMI over 26kg/m² or weight over 70kg
- o increased dose for individuals using liver enzyme inducing agents
- o severe hepatic impairment

- o individuals with previous salpingitis or ectopic pregnancy
- o lapp-lactase deficiency
- o hereditary problems of galactose intolerance
- o glucose-galactose malabsorption

Note some products may be licenced only for certain age groups (e.g. 16 years and over) – supply of these products outside the licensed age groups is permitted under this PGD

Dose and frequency of administration

Levonorgestrel 1500mcg (1 tablet) to be taken as soon as possible up to 96 hours of UPSI.

- Dose for those individuals taking enzyme inducing medicines or herbal products: An individual who requests LNG-EC whilst using enzyme-inducing drugs, or within 4 weeks of stopping them, can be advised to take a total of 3mg levonorgestrel (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. Note the effectiveness of this regimen is unknown.
- Dose for those individuals with a body mass index of more than 26kg/m² or who weigh more than 70kg: An individual who requests LNG-EC with a body mass index of more than 26kg/m² or who weighs more than 70kg can be offered a total of 3mgLNG-EC (two 1500mcg tablets) as a single dose and within 96 hours of UPSI. Note the effectiveness of this regimen is unknown.

It is unclear on what basis paragraphs 38 and 39 of the Impact Assessment are being made.

NICE Competency framework for health professionals using patient group directions

To ensure that those that develop, authorise or use PGDs do so safely, NICE has created a series of competency frameworks.¹⁶ The competency framework for health workers using PGDs comprises 3 domains with a total of 9 competencies.

These competencies are expanded upon in the NICE document and the table below lists a few of these.

Demonstrates an up-to-date knowledge about the medicine(s) included in the PGD, including its mode of action, pharmacokinetics, indication, contraindications, cautions and drug interactions (recommendation 1.5.2)

Knows how to take an appropriate medical history and medication history, including current and previously prescribed medicines in addition to non prescribed medicines, supplements and complementary remedies (recommendation 1.5.3)

Understands the effect of multiple clinical conditions, existing medication, allergies and contraindications on management options (recommendation 1.5.3)

Is able to make, or understand, the diagnosis by considering and systematically deciding between the various possibilities (recommendation 1.5.3)

Knows when to consider alternative options for treating the patient's condition, including no treatment, non-drug and drug interventions (recommendation 1.5.3)
Is able to select the most appropriate drug, dose and formulation for an individual patient (recommendation 1.5.3)
Is able to assess the risk of, and deal with, adverse events after administration of a medicine, including supportive measures for potentially life threatening adverse events (recommendation 1.5.3)
Is able to check doses and calculations to ensure accuracy and safety (recommendation 1.5.3)
Understands and applies the principles of evidence-based medicine
Is able to interpret relevant medicines information, such as the summary of product characteristics and NICE guidance (recommendations 1.5.2 and 1.5.3)
Understands the advantages and limitations of different information sources
Applies information to the clinical context, linking theory to practice
Understands the benefits and risks of alternative options for supplying and/or administering medicines, including independent prescribing, supplementary prescribing and patient-specific directions (recommendations 1.1.1 to 1.1.3)

It is clear from the above that a **basic knowledge of the basic principles** of biology, microbiology, physiology and chemistry together with basic pharmacological principles is wholly inadequate as the underpinning education from which a pharmacy technician could use a PGD.

We appreciate that there is a requirement for PGD-specific training for every PGD. However, this is predicated on a more than basic knowledge of the principles around the core science and pharmacology of medicines. This level of knowledge cannot be gained during a level 3 IEPTP which can be undertaken with a minimum requirement of just 14 hours per week over a 2-year period.

A full-time 4-year MPharm and a subsequent one year of full-time foundation training (which culminates with a gateway registration assessment) is the underpinning education upon which a pharmacist will use a PGD. The other healthcare professionals authorised to use PGDs have a minimum level 5 qualification.

The concerns recorded by many Pharmacy Technicians including “cheating of regulations”

The “leadership” body for pharmacy technicians (The Association of Pharmacy Technicians United Kingdom – APTUK) clearly support the use of PGDs by pharmacy technicians. We refer the DHSC and readers of this response to the comprehensive PDA pharmacy technician report for the full PDA discussion and appraisal around the legitimacy of APTUK to call itself a “professional leadership body”.⁷

Notwithstanding the support for this proposal by APTUK, many pharmacy technicians themselves have serious concerns around the suitability of their training to undertake wider roles.

A comprehensive report in 2016 by the University of East Anglia noted the concerns of many pharmacy technicians.¹⁷ We acknowledge that the new IETPT standards came into operation in 2017 but most of the currently registered pharmacy technicians are on the register because of the grandparent clause or the former NVQ qualification. The concerns and comments within the 2016 report are equally valid today just as they were valid in 2016.

Answers to the question regarding potential changes to training of PTs included some comments about respondents' own training. For example, this respondent had been working as a PT for 6 years and registered after July 2011:

"In my pre-registration training the modules we did at college had no real relation to the job I would be performing. There was a lot of time spent on biology and how to present things but very little of the course seemed to be about the use of medicines, their side effects or common regimens of treatment."

This PT who registered post 2011 and had 3 years' experience said:

"A lot of things that were taught at college are not used in our day-to-day working i.e. making medications from scratch - creams/ointments/powders, chemistry knowledge which is not used in our work. Pharmacokinetics and pharmacodynamics, the nervous system, biochemistry [should be included]."

The report also detailed that many pharmacy technicians working within community pharmacy had noted their lack of clinical knowledge and the barrier that this created to their career development (i.e. undertaking wider roles).

The inadequacy of the pharmacy technician's training was also noted by those practising in settings other than community pharmacy with one pharmacy technician being exceptionally frank:

"The current NVQ process is not fit for purpose and too restrictive."

Another pharmacy technician working in a hospital setting noted:

"The basic training needs to be upgraded from a NVQ3 this is really poor, to enter into the NHS on A4C Band 5 is degree level, the qualification needs to reflect this. Many of the technicians coming from community have very few skills that match those required in the NHS in a hospital setting. The distance learning course they have carried out such as Buttercups have left them poorly trained and equipped to work in an ever changing role."

And similarly, another hospital trained pharmacy technician observed the need for:

"Proper training and proper regulations that can't be cheated on."

The report also noted concern around the method of assessment:

The method of assessment was also questioned and seen as a tick box exercise:

“The course has obviously changed a lot since I did my training, and it seems that now there is a lot more emphasis on ticking boxes in relation to each module, rather than on practical experience.”

There is a significant issue around the difference between hospital and community training and subsequent practice. This was also noted in the 2016 report.

One participant suggested that hospital and community pharmacy technician roles are so different that the training should be separate:

“I did my training in community so when I transferred to hospital I found it quite daunting as it was so different. Maybe separate out the training.”

The difference between a pharmacy technician’s role in hospital and community pharmacy is distinct, and there appears to be no evidence base or assessments made of the specific roles, training and peer support that they have in the various workplaces.

Those that actively advocate for an expanded role for pharmacy technicians often speak from the perspective of a hospital setting, without knowledge or consideration of the picture in community pharmacy for example.

In feedback from PDA members, pharmacy technicians working in hospital pharmacies may be far better equipped with education and training to undertake work under a PGD, but conversely, for those working in community this would be a serious concern for them.

The proposals do not take this variation into account, and to take a broad-brush approach across all settings and regardless of education and training undertaken is a risk to patient safety.

We discuss how this difference also affects the provision of indemnity cover in our response to the Impact Assessment question later in the response.

The issue around the Pharmacy Technician course assessment.

The 2016 report noted concern around course assessment. This is of course fundamental as entry onto a regulatory register must be robust and fit for purpose.

The consultation document states that:

“Registrants must meet all these standards when they first register and complete a professional declaration.”

The GPhC has never set a common registration assessment to be taken by all pharmacy technicians at the end of the IETPT.

This is in marked contrast to the registration assessment that has to be taken by all pharmacy students who have passed exams for each year of the 4-year MPharm and who have satisfactorily completed their registration year. As an example, for the June 2023 registration assessment and despite the robust 5-year training programme the pass rate for these pharmacy graduates was just 77%.¹⁸

The GPhC commissioned its own report in 2014. Whilst we appreciate that the outcome focused IETPT 2017 may have led to changes to course design and how it is delivered there are still significant issues that are unaddressed.

It should be noted that the GPhC has recently commissioned a report on the impact of the 2017 IEPTP:

“The research should generate insight that helps us to understand the impact of the 2017 IETPT standards on the skills and performance of pharmacy technicians and the experiences of those involved in delivering and completing the current initial education and training. This will feed into our plans for educational reform, where we are looking to review the current standards in the next few years.”¹⁹

The variability between course providers is dealt with for pharmacists by the setting of a common registration assessment. This variability issue is still unresolved for pharmacy technicians.

This interviewee went on to talk about the differences between the criteria for passing exams versus assignments, with assignments in her view seeming easier to meet pass criteria. Though this was based on anecdotes, it raised, again, the issue of the mode and level of assessments that exist and their potential ability to challenge trainees to the same extent.

“[There is an issue with] the difference in the quality between [two awarding bodies named] because, again, anecdotally I’ve been told that some of the assessments or the assignments from [one] for the pass criteria are particularly minimal and it could just be filling in a word on a table, whereas the assessment for [another] is more robust.

So how do you then assure that you’ve got the same pharmacy technician on the register?”²⁰

This impact of the variability and robustness of assessment can lead to trainees passing the assessment even though they may lack an understanding of the subject and more critically they may lack the ability to apply the knowledge in practice.

“If you’ve got an online test to do, then the pharmacist could be there, or somebody else could be there supporting, and maybe helping with the answers,

and not realising...and because obviously they're not trained assessors, they're not trained in teaching, but they know the job, so they assume ... that their member of staff understands something, and they actually don't.

I have seen that before as well, where they're kind of almost given the answers, but their explanation isn't really that great.

Also, when somebody's doing an assignment, and they're just writing it up and getting it sent off, again it could be something that they've kind of almost learnt by rote, and they're regurgitating an answer, but the understanding and practice isn't there."²⁰

This is fundamentally important. Learning by rote and lacking the capacity to apply even the basic principle of pharmacology has the potential to have significant patient impact. The 2016 report observed:

During the focus groups participants talked about their experiences of mentoring students and some of the skills that were lacking. One participant felt that even attending college did not necessarily equip trainees for the PT role and that making the link between drug and patient did not always happen:

"So even when they go to college so I'll stand in the dispensary and obviously I'll go and work in the dispensaries and I'll ask my students 'what does Warfarin do?'

And they can't...and they've just done that thing... So you'll just give them a prescription and go 'what do you think is wrong with that patient?' And often they can't tell you because they can't necessarily make that jump between the drug on the page and what could be wrong with that patient."¹⁷

A fuller, more comprehensive discussion on this issue can be found within the 2019 PDA Technician Report.

This proposal is to allow registered pharmacy technicians to supply and administer medicines using a PGD.
Do you have additional information in support of this proposal? (maximum 150 words)

In our online submission which was limited to 150 words we stated:

We cannot support this proposal for the reasons outlined in this response.

Do you have additional information for why this proposal should not go ahead?
(maximum 150 words)

In our online submission which was limited to 150 words we stated:

We have significant and coherent reasoning as to why this proposal must not go ahead. To capture this within 150 words (as with the other questions) is not possible.

Therefore this online PDA submission should be considered together with our fuller emailed response and also our comprehensive Technicians Report published in 2019 - <https://www.the-pda.org/wp-content/uploads/FINAL-PT-Report-28-02-19.pdf>

Taken together these form the full PDA response to this consultation for consideration by the DHSC.

The law as regards to the operation of a retail pharmacy is clear. The Responsible Pharmacist RP has to secure the safe and effective operation of the pharmacy. Accountability for the actions of PTs working under a PGD within retail pharmacy needs to be clarified as the RP should not be liable or responsible were a patient to come to harm following a service independently provided by a PT using a PGD.

The Responsible Pharmacist (RP) has a legal duty to secure the safe and effective operations of a registered pharmacy. This is an overarching duty, and it is unclear where the accountability and responsibility for allowing a pharmacy technician to use a PGD would lie.

Community pharmacy across the UK is reliant on a locum workforce. This situation has arisen for a multitude of reasons but feedback from our 37,000 members indicates that many pharmacists have left employment to become locums due to the working conditions in many community pharmacies. Locum pharmacists are free to choose the hours they work and the places where they work and without the pressure to reach unrealistic targets (for example the number of PGDs completed in one day).

These locums will not have knowledge of the staff and their competencies and would not be able to determine whether they are able to use a PGD. The quality of “pre-information” provided by many locum agencies and pharmacy owners (including information about staffing levels and the qualifications of staff) is exceptionally poor.²¹ This has significant impact on how the pharmacy operates as it creates an inherent tension between the locum RP and staff due to the lack of full and proper information.

This situation could be compounded or aggravated were proposals to embed the routine absence of the RP taken forward by the GPhC and on matters relating to supervision by the DHSC. We understand that there may be imminent consultations on all these and other matters including setting standards for Superintendent Pharmacists.

Existing case law places the duty of supervision on a pharmacist and the 1968 Medicines Act places the responsibility to secure the safe and secure operations of the pharmacy on a RP so the impact of allowing pharmacy technicians to use PGDs must be considered in this context.

This is an issue which needs serious consideration, and we need to consider the impact of this consultation with the matters outlined above.

We could at the extreme end of the spectrum be in a situation where an absent locum responsible pharmacist is being coerced by a pharmacy owner (as a business case) to allow a pharmacy technician to undertake complex PGDs.

This consultation proposal paves the way for such a scenario, and this cannot be in the public interest, nor would it be safe for patients.

Do you agree or disagree that the consultation stage impact assessment gives a realistic indication of the likely costs, benefits and risks of the proposal?

Agree

Disagree ✓

Don't know

If you have any additional information to support your answer, please provide details (maximum 150 words).

In our online submission which was limited to 150 words we stated:

The impact assessment (IA) is not fit for purpose. The scenario around the supply of Emergency Hormonal Contraception (EHC) states PTs have “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”. This is patently incorrect. The underpinning knowledge taught to PTs is basic and inadequate to provide a safe EHC or any other service.

Notably, the IA focuses on community pharmacy (CP) and not other settings (hospitals, prisons etc). Most CPs do not employ registered PTs – the 2022 CP workforce survey in England (over 11,000 CPs) employed around 5,000 FTE PTs. Similarly in Scotland 780FTE PTs are employed in around 1,300 CPs.

We would also like to see how the workings leading to total cost of £11 billion and a £1.9 billion net cost benefit for this policy. These figures are not evidenced or referenced.

The impact assessment, *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 was not published alongside the consultation. Having to search for it online is inadequate.

The focus of the IA seems to be around community pharmacy. However, we know from community workforce data published in England ¹⁰ that in 2022 there were 11,073 pharmacies but only 5,252 FTE pharmacy technicians were employed in these. The figures in Scotland ²² indicate a similar picture. It is unclear how this has been factored into the financial modelling used in the IA.

Paragraph 29 states that pharmacists spend between 409 – 818 hours each year using PGDs. There is no evidence presented to support this figure. It is clear from this paragraph that this PGD proposal is about role substitution and not about skill-mix,

The IA also puts forward the argument that pharmacy technicians not being able to operate under a PGD limits the support they can provide, and this creates additional costs to pharmacies, potential delays to patients and inefficiencies within community prescribing teams. There is no consideration of patient safety and the financial impact of potential patient incidents caused by inappropriate provision of medicine, or ensuring all pharmacy technicians are trained to the necessary standards. There is no evidence presented to support that delays are occurring to patients because pharmacy technicians cannot use PGDs.

Paragraph 26 of the IA notes that

“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.”

The PDA, as the largest provider of indemnity insurance for pharmacists across the UK, is in regular contact with a panel of underwriters and risk carriers. From discussions with them, it would appear that they are not aware of pharmacy technicians being given the rights to deliver PGDs under the proposals stated in the consultation. They have significant concerns over the probity of the involvement of pharmacy technicians in PGD's under the current proposals in community pharmacy bearing in mind the problems with the current community pharmacy infrastructure, and the additional quality, training and professional considerations as they represent a large scale, significant and material uplift in the community pharmacy risk profile.

It would appear that they do not share the risk appetite being demonstrated by the DHSC and those already providing indemnity to pharmacy technicians will likely be

unprepared to provide cover related to the risk of pharmacy technicians delivering PGDs; especially those in the community pharmacy setting.

In light of these findings, the PDA is seeking clarification from DHSC about what discussions and assessments have been undertaken to underpin the proposals based on indemnifying this proposed activity, especially in a community pharmacy setting.

The safety considerations are very material and appear to have not enjoyed the detailed consideration that they deserve as evidenced by the approach being taken; the proposal appears not to have been properly thought through.

There may be serious consequences whereby indemnity cover cannot be provided for pharmacy technicians to undertake PGDs, and if the proposals go ahead, the government will have established a very dangerous arrangement where some employers may push pharmacy technicians to undertake the activity without the necessary indemnity arrangements being properly put in place. This will represent another direct and very serious risk to the public; as well as putting under pressure the regulatory principles that pharmacy technicians are meant to abide by.

The PDA strongly believes that when patient safety is at stake, proposals must be based on a strong foundation of proper skill mix, education, training and governance, and not purely ideology and cost saving.

NI respondents: equality and rural screening

In Northern Ireland new policies must be screened under Section 75 of the Northern Ireland Act 1998, which places a statutory duty on public authorities to mainstream equality in all its functions so that equality of opportunity and good relations are central to policy-making and service delivery. In addition, new or revised policies must be rural-proofed in line with the Rural Needs Act (NI) 2016, which requires public authorities to have due regard to rural needs.

We do not consider that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in NI.

If you agree or disagree, we welcome views on this point (maximum 150 words).

In our online submission which was limited to 150 words we stated:

However, as PTs are not registered in NI we cannot be sure of the impact.

The requirements for entry onto any potential PT register has not been confirmed. Over 50% of the current GB registered PTs entered the register via the grandparent clause and details about their training is still unclear. Any future entry onto the Pharmaceutical Society of Northern Ireland PT

register must be based on a robust process with the full and complete record of training which the potential PT registrant has undertaken.

There may be potential impacts in that by allowing a level 3 occupation of PTs to undertake activities currently undertaken by pharmacists this may reduce access to services being provided by a level 7 educated pharmacists in rural areas.

For completeness we are including our response to the further questions at the end of the online consultation.

We have a few questions we would like to ask to help us improve future consultations.

How satisfied are you with the consultation process? (optional)

Very satisfied

Satisfied

Dissatisfied

Very dissatisfied ✓

How did you hear about the consultation? (optional)

Social media

Received an email ✓

Word of mouth (family, friend or colleague)

Direct communication from third sector organisation or regulatory organisation

Broadcast news (TV or radio)

GOV.UK or other government website

Newspaper (online or print)

Website (non-government)

Trade magazine

Other

Do you think we could improve this process? (optional)

1/ Consultations should not limit the responses to 150 words. This arbitrary limit removes the possibility to provide a full and considered response. It almost feels like the DHSC is not seeking full considered responses.

2/ The Impact Assessment was not published on the consultation page with the consultation. This is not acceptable especially as this particular impact assessment is very poor. Impact assessments must always be published with the consultation or a link given to where it can be found.

3/ Consultations such as this form usually form part of a wider DHSC policy agenda. This particular PGD consultation has to be considered as part of the wider DHSC pharmacy agenda - for example the DHSC is considering major changes around how pharmacist supervision is discharged in pharmacy settings. Consultations such as this

PGD consultation must also provide details about other parallel streams of activity irrespective of whether the DHSC considers that there is an impact or not.

References

- ¹ Pharmacy: Delivering a Healthier Wales - The 2030 Vision for Wales
<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Policy/Pharmacy%20Vision%20English.pdf?ver=2019-05-21-152234-477>
- ² Royal Pharmaceutical Society Scotland | National Pharmacy Technician Group Scotland - January 2022 - Pharmacy 2030: a professional vision
<https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Scotland/Pharmacy%202030%20vision/Pharmacy%202030%20Full%20professional%20vision%20Jan22.pdf?ver=WD2LOOTwG4ejGBfEPC6D0w%3d%3d>
- ³ Office for National Statistics - Earnings and hours worked
<https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours>
- ⁴ 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
https://web.archive.org/web/20231002155507/https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1179386/impact-assessment-9597-adding-pharmacy-technicians-to-list-of-registered-health-professionals-able-to-supply-medicines-under-PGDs-august-2023.pdf
- ⁵ Patient group directions - NICE guideline - Methods, evidence and recommendations - March 2017
<https://www.nice.org.uk/guidance/mpg2/evidence/full-guideline-pdf-4420760941>
- ⁶ APTUK Position Statement on Pharmacy Technicians being added to the list of Healthcare Professionals who can supply medicines against a Patient Group Direction
<https://www.aptuk.org/pharmacy-technicians-supplying-medicines-through-a-patient-group-direction-pgd>
- ⁷ Pharmacy technicians: an assessment of the current UK landscape, and proposals to develop community pharmacist and pharmacy technician roles and skill mix to meet the needs of the public
<https://www.the-pda.org/wp-content/uploads/FINAL-PT-Report-28-02-19.pdf>
- ⁸ Approved courses and qualifications for pharmacy support staff
<https://www.pharmacyregulation.org/education/approved-providers-education-and-training/approved-courses-support-staff#Accredited%20support%20staff%20courses>
- ⁹ Pharmacy Technician and Pharmacy Support Staff Workforce Development Strategy
<https://www.hee.nhs.uk/sites/default/files/documents/Pharmacy%20Technician%20and%20Pharmacy%20Support%20Staff%20Workforce%20Development%20Strategy.pdf>
- ¹⁰ Community Pharmacy Workforce Survey
<https://www.data.gov.uk/dataset/09aa8f38-547a-46b7-a117-2cb710ad939b/community-pharmacy-workforce-survey>
- ¹¹ Standards for the initial education and training of pharmacy technicians - October 2017
https://www.pharmacyregulation.org/sites/default/files/standards_for_the_initial_education_and_training_of_pharmacy_technicians_october_2017.pdf

¹² Standards for the initial education and training of pharmacists

https://www.pharmacyregulation.org/sites/default/files/document/standards-for-the-initial-education-and-training-of-pharmacists-january-2021_final-v1.3.pdf

¹³ PHARMACY TECHNICIAN (INTEGRATED)

<https://www.instituteforapprenticeships.org/apprenticeship-standards/pharmacy-technician-integrated-v1-1>

¹⁴ 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

https://web.archive.org/web/20231002155507/https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1179386/impact-assessment-9597-adding-pharmacy-technicians-to-list-of-registered-health-professionals-able-to-supply-medicines-under-PGDs-august-2023.pdf

¹⁵ PATIENT GROUP DIRECTION (PGD) For Community Pharmacists - Supply and/or administration of levonorgestrel 1500micrograms tablet(s) for emergency contraception- Version Number 2.0 - PGD Expiry date: 28th February 2026

https://www.derbyshiremedicinesmanagement.nhs.uk/assets/Clinical_Guidelines/Patient_Group_Directions/PGD_Levonorgestrel_1500mcg_Tablets_Community_Pharmacies.pdf

¹⁶ Patient group directions - Medicines practice guideline [MPG2] - Last updated: 27 March 2017- Tools and resources

<https://www.nice.org.uk/guidance/mpg2/resources>

¹⁷ Identifying the Roles of Pharmacy Technicians in the UK - Final Report, September 2016

<https://web.archive.org/web/20231002105301/https://www.aptuk.org/static/pdf/739ca515c1bcc964c8528cc9e172766a.pdf>

¹⁸ GPhC announces results for June 2023 registration assessment - 28 July 2023

<https://www.pharmacyregulation.org/news/gphc-announces-results-june-2023-registration-assessment>

¹⁹ General Pharmaceutical Council: GB-London: GPhC074 Research on the Standards for the Initial Education and Training of Pharmacy Technicians

<https://www.delta-esourcing.com/delta/respondToList.html?noticeId=783625737>

²⁰ The quality of pharmacy technician education and training: A report to the General Pharmaceutical Council - November 2014.

<https://web.archive.org/web/20231002125056/https://www.pharmacyregulation.org/sites/default/files/document/quality-of-education-training-for-pharmacy-technicians-uom-report.pdf>

²¹ In the latest member voice, a PDA member with over 30 years' experience of working as a locum in community and hospital pharmacy shares their views on returning to the UK to practice after three decades in Australia.

<https://www.the-pda.org/worlds-apart/>

²² Community Pharmacy Survey 2022 - NHS Education for Scotland

<https://turasdata.nhs.scot/data-and-reports/other-workforce-statistics/pharmacy-workforce/pharmacy-community-survey-2022/?pageid=8399>