Publications approval reference: PAR145

Patient and public summary of:

Consultation on the proposal for the supply and administration of medicines using patient group directions by clinical scientists across the United Kingdom

October 2020

This is a summary of the full consultation guide entitled '*Consultation on the proposal for the supply and administration of medicines using patient group directions by clinical scientists across the United Kingdom'*.

This summary guide is much shorter and **does not** contain all the detail on the proposed changes.

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please email england.cpomedicinesmech@nhs.net.

Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and

- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Contents

1 Introduction to the consultation

1.1 What are we consulting on?

In collaboration with the Scottish, Welsh and Northern Ireland governments, we are consulting on a proposal to enable clinical scientists to use patient group directions (PGDs) to supply and administer medicines to their patients.

Patient group directions (PGDs) are written instructions for medicines, including certain controlled drugs, to be supplied and/or administered by health professionals to patients who share the same medical condition or other features. They contain information about which health professionals can supply or administer the medicine, which patients they can see, and when they should involve a doctor. PGDs are NOT a type of prescription.

There are two options for consideration in this consultation:

> **Option 1**: no change.
>
> **Option 2:** enabling the supply and administration of medicines using PGDs by clinical scientists

The proposed changes require amendment to both the Human Medicines Regulations and the Misuse of Drugs Regulations 2001. The Human Medicines Regulations apply UK-wide so subject to the agreement of Ministers, changes to them will apply across the four countries. The Misuse of Drugs Regulations apply only to England, Wales and Scotland; the Misuse of Drugs (Northern Ireland) Regulations 2002 will need to be amended separately and this will be undertaken by the Department of Health in Northern Ireland.

Should legislation be amended, the changes would apply in any setting in which clinical scientists work and where PGDs can be used.

1.2 Why are the proposed changes being considered?

Clinical scientists are currently able to use patient specific directions (PSDs) to administer or supply a medicine. A PSD is a written instruction to administer a medicine to a named patient who has been assessed by the authorised prescriber who then prescribes the medicine.

The use of PGDs by clinical scientists would bring many benefits to both patients and the healthcare system. The clinical scientist role has expanded over the past 10 years with some clinical scientists now undertaking responsibilities previously only carried out by doctors. Some clinical scientists are undertaking diagnostic tests directly with patients and recommending treatments based on the test results.

Currently, other health professionals such as doctors need to be involved in the patient's care to prescribe the medicines the patient needs. The proposed use of PGDs would mean that a greater number of patients could receive the medicines they need from the clinical scientist undertaking their care, without having to also see other health professionals such as doctors, to prescribe the medicines needed.

Further information on the benefits of this proposal and potential risks, and measures in place to manage the risks is presented in section 4.3 and section 4.5 of the full consultation guide respectively.

1.3 Supporting documents

There are several national resources published by the National Institute of Clinical Excellence (NICE) which are related the use of PGDs and which clinical scientists will be expected to comply with. These include

- *Patient Group Directions Medicines Practice Guideline*[1]
- *Competency framework: For people developing and/or reviewing and updating patient group directions*[2]
- *Competency framework: for people authorising patient group directions*[3]
- *Competency framework: for health professionals using patient group directions*[4]

In addition, a *Consultation Stage Impact Assessment* has been developed which focuses on what impact the proposed policy change is likely to have and highlights the costs, benefits and risks of the proposed changes.

1.4 What you will be asked about

The consultation questions ask:

- what you think about the proposal and whether you have additional information on any aspects not already considered as to why the proposal SHOULD or SHOULD NOT go forward
- what you think about the *Consultation Stage Impact Assessment* which accompanies the proposal
- whether the proposal will have a positive or negative impact on people who are affected by equality and health inequality issues
- about yourself or your organisation so that the views of different groups can be better understood.

The consultation will run for 8 weeks and will close on **10th December 2020.**

You can find a glossary used in this document in section 8 of this guide.

2 Background

A scoping project was undertaken in 2015 by NHS England and looked at the need for some regulated health professions to supply and administer medicines to their patients. The report of the project made a number of recommendations, including that the patients treated by clinical scientists could benefit from them being able to use PGDs.

[1] NICE (2017) *patient group directions: medicines practice guideline*
[2] NICE (2017) *Patient group directions: tools and resources*
[3] NICE (2017) *Patient group directions: tools and resources*
[4] NICE (2017) *Patient group directions: tools and resources*

The Chief Professions Officers' Medicines Mechanisms (CPOMM) programme of work started in April 2017 to take forward the recommendations.

We are leading consultations on proposals to change the medicines responsibilities for eight health professions, as follows:

- enabling **dental hygienists** and **dental therapists** to supply and administer specific medicines under exemptions within medicines legislation
- enabling **biomedical scientists**, **clinical scientists** and **operating department practitioners** to supply and administer medicines using patient group directions
- amending the current lists of controlled drugs that **podiatrist** and **physiotherapist** independent prescribers are legally able to prescribe
- amending the list of medicines that **paramedics** can administer in emergency situations using exemptions within medicines legislation.

All the proposals share the same aim, to make it more convenient and safer for patients to get the medicines they need at the time and place when they need them. This will reduce the need for appointments with additional health professionals just to receive the medicines needed, which often results in unnecessary delays to the start of treatment.

The consultations can be found on the NHS England consultation hub website.

3 The clinical science profession

All clinical scientists must be registered with the Healthcare Professions Council (HCPC), the regulatory body which sets the standards that clinical scientists are expected to meet. The main training programme for clinical scientists working in the NHS to be able to register with the HCPC is the Scientist Training Programme (STP)[5]. Once registered, clinical scientists must show that they are completing regular education, and that they continue to practise both safely and effectively within their scope of practice, in order to maintain their registration. There are currently 6424[6] clinical scientists registered with the HCPC in the UK.

Clinical scientists perform specialist investigations and tests to diagnose and treat or control some diseases. They are often involved in research to help improve the quality of life for patients. They also advise doctors on tests and interpret data using their understanding of disease processes.

Although a great deal of work is carried out in the laboratory, clinical scientists are increasingly working face-to-face with patients in clinical settings. These settings range from small clinics in the community to large clinics in hospitals. Clinical scientists also work in schools, charities, private clinics and universities. Most clinical scientists are employed within the NHS.

[5] National School of Healthcare Excellence *NHS Scientist Training Programme*

[6] Health and Care Professions Council *registrants by profession & route & gender* September 2020

The profession of clinical scientist can be subdivided into four main areas of practice:

- physiological sciences
- life sciences
- bioinformatics
- physical sciences

Within each of the main areas, clinical scientists specialise even further, for example, audiology (hearing), vision or cardiology (heart).

Clinical scientists may work partly or completely in independent practice. No matter where they work, they must always meet the same high standard as set by the HCPC. Likewise, their employers must use the same standard of systems and checks to ensure patient safety.

There are several professional bodies that represent clinical scientists[7].

4 Case for change

4.1 Identification of viable options

The report of the 2015 NHS England scoping project indicated the legal mechanism of administration, supply or prescribing that best fits the professions considered, and prioritised certain professions based on current NHS priorities. The report recommended that further work should be undertaken to enable clinical scientists to supply and administer medicines using PGDs. This is because, whilst clinical scientists are able to supply and administer medicines using PSDs, they often still need to refer patients to doctors to receive the medicines they need.

Two options have been considered:

Option 1- no change
There would be no change to legislation; clinical scientists would continue to use PSDs to supply and administer medicines to their patients.

Benefits
The existing legislation works well for a few patients whose medicines needs can be anticipated in advance of their treatment or where a prescriber is always available.

Limitations
Existing arrangements may not best support the needs of the majority of patients that clinical scientists see who need a different medicine than anticipated. PSDs also require direct input from an independent prescriber and can therefore be restrictive when a prescriber is not available or if the service provided is not led by a prescriber. This often results in patients needing to wait for another health professional, just to receive the correct medicines.

[7] Academy of Healthcare Science Clinical science professional bodies

More detail on the impact of this option and the limitations of the current mechanism available to clinical scientists can be found in section 4.2 of the full consultation guide.

Option 2: proposal to amend legislation to enable clinical scientists to supply and administer medicines using PGDs.

Benefits
Patients who are treated by clinical scientists would be able to receive the medicines they need without additional appointments with a prescriber which often results in delays to receiving medicines. The proposed use of PGDs by clinical scientists would also enable better use of their skills and free up the time of other healthcare professionals, such as doctors, so that they can see patients who would benefit more from an appointment with a doctor.

Further information about the anticipated benefits can be found in section 4.3 of the full consultation guide.

Limitations
Should legislation be amended, the limitations of the PGD mechanism[8] may mean that not all the patients that clinical scientists see will benefit from the proposed changes to legislation, such as those requiring medicines with variable dosing.

4.2 Management of potential risks associated with the proposal

Whenever there is any extension of medicines supply, administration and prescribing responsibilities to regulated health professions there will be associated risks with the enhanced responsibilities. Identification of the risks informs the development of governance and patient safety measures that are necessary to maintain patient safety.

There are a number of potential risks to the proposal to enable clinical scientists to supply and administer specific medicines using PGDs. The risks perceived are the same as those for other professions that use PGDs to supply and administer medicines. As such, they can be managed by the governance and patient safety measures that are already in place as described in section 5 below.

The potential risks of the proposal are included in table 1 in the full consultation guide.

5 Governance and patient safety

5.1 Safe use of PGDs

If the proposal is approved and legislation amended, all registered clinical scientists would be eligible to supply and administer medicines using PGDs. However, it would be for local organisations to agree whether there would be a need for clinical scientists to use PGDs. The decision would be based on national guidelines[9] and local policies.

[8] NICE (2017) *Patient group directions: medicines practice guideline*
[9] NICE (2017) *patient group directions: medicines practice guideline*

PGDs are locally written, authorised and used. Organisations already have policies and procedures in place for other professions who use PGDs and clinical scientists would be expected to comply with these.

For further information about the governance and safe use of PGDs, see section 5.1 of the full consultation guide.

5.2 Training to use PGDs

All professions that can currently use PGDs to supply and administer medicines are strongly recommended to undertake additional training before using PGDs in practice. Clinical scientists would also be expected to undertake the same training should they be able to use PGDs in the future.

After completing the required training in the use of PGDs, they will also be required to keep their knowledge and skills up to date. Clinical scientists using PGDs must show they are undertaking the appropriate continuing professional development and must demonstrate that they continue to practise both safely and effectively.

5.3 Communication of decision to supply or administer medicines using PGDs

If the proposed changes are approved, before supplying and/or administering medicines to a patient using a PGD, clinical scientists would have to assure themselves that they have all the information they need to make a safe and effective decision. Clinical scientists have access to the patient's medical records but would also have to obtain additional information from the patient and other health professionals as required. Clinical scientists would have to record in the medical record that this information has been checked and that the medicine being supplied and/or administered is suitable for the patient. When supplying or administering controlled drugs using PGDs, clinical scientists must follow any recording requirements specific to the scheduling of the medicine.

Should PGDs be used, a statement that the medicine has been supplied or administered using a PGD should be included when the medicine is recorded in the patient's notes. If any medicines have been supplied to the patient to take at home, then it is proposed that the GP would also be informed.

6 Equality and health inequality considerations

We have undertaken an Equality and Health Inequalities Screening Tool in accordance with NHS England requirements. A review of the screening tool by the specialist NHS England team indicated that a full Equality and Health Inequalities assessment was not required prior to the launch of the consultation but will be undertaken alongside the consultation to collate responses.

During the consultation we will assess if the proposal will make it easier for people to get the medicines they need when they need them, avoiding the need for people to see additional health professionals just to receive medicines. This may remove or minimise disadvantages suffered by vulnerable people when accessing medicines.

6.1 Public sector equality duty

Public bodies across England, Scotland and Wales have legal obligations under the Equality Act 2010[10], and are specifically required to consider the aims of the Public Sector Equality Duty[11], as set out at section 149 of the Equality Act 2010 when making decisions. This means that NHS England and NHS Improvement should understand the potential effect of the proposal on people with characteristics that have been given protection under the Equality Act 2010, especially in relation to their health outcomes and the experiences of patients, communities and the workforce. This will help us to consider whether the policy or practice will be effective for all people.

As this consultation is UK-wide, appropriate consideration has also been given to the requirements of the Northern Ireland Act 1998[12].

6.2 Health inequality duties

NHS England and NHS Improvement also have duties to consider the need to reduce health inequalities between patients' access to, and outcomes from healthcare services, and to ensure services are provided in an integrated way.

The consultation process provides a further opportunity to consider the potential positive and negative impact of the proposed changes on equality and health inequalities and to seek the views of responders. We and the devolved administrations will give due regard to responses received and we will be developing a fuller Equality and Health Inequalities impact assessment alongside the consultation.

For further information about our duties, see section 6 in the full consultation guide.

7 Consultation format

7.1 Who can respond to this consultation?

Everyone is welcome to respond. We hope to hear from the public, patients, patient representative groups, carers, voluntary organisations, healthcare providers, commissioners, doctors, pharmacists, healthcare scientists, allied health professionals, nurses, regulators, the Royal Colleges and other representative bodies.

[10] Equality Act 2010
[11] Public Sector Equality Duty 2011
[12] Northern Ireland Act 1998

We are grateful to individuals and organisations who take the time to respond to this consultation.

7.2 How to respond

If you would like to respond to this consultation you can do so by:

- completing the online survey
- asking for a paper copy of the consultation response form to be posted to you by contacting: england.cpomedicinesmech@nhs.net

  Please complete this form and return it to:

  CPOMM Programme Team
  NHS England and NHS Improvement
  5W06 Quarry House
  Leeds
  LS2 7UE

Responses should be sent to arrive no later than 10th December 2020.

7.3 Alternative formats

- A paper copy of this summary consultation guide is available on request. It can also be made available in formats such as large print and easy read, and may be available in alternative languages, upon request. Please contact england.cpomedicinesmech@nhs.net.

7.4 Engagement events

Engagement events will be held online during the consultation period. These will provide an opportunity for those attending to find out more about the proposals and the consultation process.

To register or find out more information about any of these events please go to: https://www.england.nhs.uk/medicines-2/chief-professions-officers-medicines-mechanisms-programme/.

7.5 How your responses will be used

Following close of the consultation, we will look at all responses received, and a summary of the responses will be published on the NHS England website.

Under the General Data Protection Regulation, NHS England will be data controller for any personal data you provide as part of your response to the consultation. NHS England has statutory powers they will rely on to process this personal data which will enable them to make informed decisions about how they exercise their public functions.

If you respond as an individual, we will anonymise your response but we may publish your response in part or full unless you tell us not to. If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full unless you tell us not to. If you would like any part of your response to stay confidential, you should explain why you believe the information you have given is confidential. NHS England may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it but we cannot guarantee that confidentiality can be maintained in all circumstances.

7.6 Next steps

The proposed changes to medicines legislation and the findings of the consultation will be presented to the Commission on Human Medicines who make recommendations to Ministers regarding changes to the Human Medicines Regulations. Subject to the agreement of the proposed changes by Ministers; the Medicines and Healthcare products Regulatory Agency (MHRA) will make the necessary amendments. The Human Medicines Regulations apply UK-wide so changes to them will apply across the four countries.

As this proposal is also in relation to controlled drugs, changes to the Misuse of Drugs Regulations are also required. The proposed changes to medicines legislation and the findings of the consultation will be presented to the Advisory Council on the Misuse of Drugs who makes recommendations to Ministers regarding changes to the Misuse of Drugs Regulations. Subject to the agreement of Ministers, the Home Office will then make the necessary amendments.

The Misuse of Drugs Regulations apply only to England, Wales and Scotland; the Misuse of Drugs (Northern Ireland) Regulations 2002 will need to be amended separately and this will be undertaken by the Department of Health in Northern Ireland.

If all elements of the proposal are approved and all relevant organisations are in a position to complete their elements of the work at the earliest possible point without delay, the proposed changes to the Human Medicines Regulations could come into force in 2021.

Each of the four devolved administrations is responsible for making amendments to the NHS pharmaceutical regulations in their own country. The NHS regulations in that country must be amended before the changes can be implemented. Changes to NHS regulations for the implementation of the amendments in Scotland, Wales and Northern Ireland and the resultant focus and pace of this in each respective country are matters for each of the devolved administrations.

8 Glossary

Term	Explanation
Administration of medicines:	Process by which a medicine is introduced into, or applied onto, the patient's body.
Chief Professions Officers' Medicines Mechanisms (CPOMM) Programme:	An NHS England and NHS Improvement programme of work to extend the supply, administration or prescribing responsibilities to regulated health professions where there is an identified need and benefit to patients. The programme aims to make it easier for people to get the medicines they need when they need them, avoiding the need for people to see additional health professionals just to receive medicines.
Commission on Human Medicines:	Advises the government on the safety, effectiveness and quality of medicinal products, and on changes to medicines law.
Continuing professional development (CPD):	Activities which help health professionals continue to learn and develop throughout their career to keep their skills and knowledge up to date so they are able to practise safely and effectively.
Department of Health and Social Care (DHSC):	The central government department with responsibility for leading the nation's health and social care system to help people live more independent, healthier lives for longer.
Health and Care Professions Council (HCPC):	The regulator of 16 different health and care professions including clinical scientists. It maintains a register of health and care professionals that are fit to practise in the UK and is responsible for setting the standards of education, proficiency, conduct, performance, character and health for these professionals.
Medicines and Healthcare products Regulatory Agency (MHRA):	Responsible for regulating all medicines and medical devices in the UK by ensuring they work and are as safe as possible. They are also responsible for making changes to medicines legislation that have been agreed by government. The MHRA is a part of the DHSC.
Patient group direction (PGD):	A written instruction for medicines to be supplied and/or administered by groups of health professionals to groups of patients. They contain information about which health professionals can supply or administer the medicine, which patients they can see, and when they should involve a doctor.
Patient specific direction (PSD):	A prescriber's written instruction for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.
Supply of medicines:	The processes undertaken, in response to formal orders, to issue medicines directly to the patient to take away. Patients then administer the medicine to themselves or allow others to help them.

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