Publications approval reference: PAR145

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 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.

A patient and public summary version of this consultation guide is available.

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?

This consultation is on a proposal to enable clinical scientists to use Patient Group Directions (PGDs).

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.

This UK-wide consultation is being led by us on behalf of the four nations and relates to the proposal to enable clinical scientists to use patient group directions (PGDs) to supply and administer medicines directly to patients in the course of their professional practice.

PGDs are written instructions for medicines, including certain controlled drugs, to be supplied and / or administered by groups of health professionals to certain groups of patients without a prescription or patient specific direction[1]. PGDs are a supply or administration mechanism and are NOT a form of prescribing. Further detail about the mechanism can be found in appendix D.

There are two options for consideration in this consultation:

Option 1: no change.

Option 2: enabling the supply and administration of medicines using patient group directions by clinical scientists

The proposed changes require amendment to both the Human Medicines Regulations 2012 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 throughout the UK, in any setting in which clinical scientists work and PGDs are permitted including the NHS, independent and voluntary sectors.

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

You can find a glossary of terms used in this consultation guide in section 9

1.2 Why are the proposed changes being considered?

The proposed use of PGDs by clinical scientists to supply and administer medicines would bring many benefits both to patients and the wider system, by facilitating the redesign of

[1] NICE (2017) *Patient group directions: medicines practice guideline*

services which are focussed on enhancing the quality of patient care whilst also increasing capacity through effective use of the workforce.

- A greater number of patients would be able to receive the care and medicines they need from the clinical scientist, without having to also see a prescriber.
- The clinical scientist scope of practice has increased significantly over the past 10 years with some now undertaking responsibilities previously only performed by doctors.
- Some clinical scientists are undertaking point of care testing (diagnostic testing at or near the point of care with the patient) and recommending treatments based on the test results which may currently require the involvement of an additional health professional to supply or administer the medicine.
- There is a need for the use of PGDs to support the autonomy of clinical scientists and advances in clinical science practice.

Further information about the benefits of this proposal is presented in section 4.3. Potential risks and measures in place to manage the risks can be found in section 4.5.

1.3 Who has been involved?

This consultation guide has been developed in partnership with Department of Health and Social Care; the Medicines and Healthcare products Regulatory Agency; the Northern Ireland Department of Health; the Scottish Department of Health and Social Care and the Welsh Department of Health and Social Services.

The professional bodies representing clinical scientists in the UK have collaborated in the development of this consultation guide and the documents that accompany it.

1.4 Supporting documents

There are several national resources published by the National Institute of Clinical Excellence (NICE) to support training and competency for use of PGDs by all health professionals involved in the writing, reviewing and authorisation of PGDs and those who operate under them. Clinical scientists would be expected to comply with these as national guidance. These include:

- *Patient Group Directions Medicines Practice Guideline*[2]
- *Competency framework: For people developing and / or reviewing and updating patient group directions*[3]
- *Competency framework: for people authorising patient group directions*[4]
- *Competency framework: for health professionals using patient group directions*[5]

1.4.1 Consultation Stage Impact Assessment

Impact assessments are an integral part of the policy making process; the purpose of an impact assessment is to focus on why the proposed intervention is necessary, what impact the policy change is likely to have and the highlighting of costs, benefits and risks. The

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

Consultation Stage Impact Assessments contains evidence of the actual (where available) and estimated costs and benefits associated with the proposal. The consultation is an opportunity to gather additional evidence to further inform the costs, benefits and risks of the proposal.

1.5 The questions being asked

Question 1
Should amendments to legislation be made to enable clinical scientists to supply and administer medicines to their patients using patient group directions?

Question 2
Should amendments to legislation be made to enable clinical scientists to supply and administer controlled drugs to their patients using patient group directions?

Question 3
Do you have any additional information on any aspects not already considered as to why the proposal to enable clinical scientists to supply and administer medicines using patient group directions SHOULD go forward?

Question 4
Do you have any additional information on any aspects not already considered as to why the proposal to enable clinical scientists to supply and administer medicines using patient group directions SHOULD NOT go forward?

Question 5
Does the *Consultation Stage Impact Assessment* give a realistic indication of the likely costs, benefits and risks of the proposal?

Question 6
Do you think that this proposal could impact (positively or negatively) on any of the protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998?

Question 7
Do you feel that this proposal could impact (positively or negatively) on health inequalities experienced by certain groups?

You will also be asked questions about yourself and / or your organisation so that the views of different groups can be better understood.

2 Background

2.1 Context

The Chief Professions Officers' Medicines Mechanisms (CPOMM) programme is set in the context of the current direction of the NHS which puts patients and the public at the heart of everything we do. The Five Year Forward View[6] set out the vision for the future of the NHS in England, a future in which access to health care is intuitive and simplified. The NHS Long Term Plan[7] envisions integrated care systems for England; within which redesigned services can enable a future where care can be personalised when people need it and can be joined-up with fewer appointments with health professionals to receive it.

We are leading a number of key programmes of work which aim to put in place the infrastructure to make the vision a reality. The programmes include the Medicines Value Programme, which has been set up to improve health outcomes from medicines and ensure that the NHS in England gets the best value from the NHS medicines bill. Whilst the Medicines Value programme is focused on the NHS in England, similar types of work are taking place in Scotland, Wales and Northern Ireland.

The CPOMM programme aims to enable the selected professions to maximise their ability to improve the patient's care, experience and safety. Optimising medicines and improving access to the right medicines whilst maintaining safety for patients would also be consistent with the government's policy to focus on improved outcomes for all and to transform the way the NHS provides care. The CPOMM programme also supports the achievement of a number of current ambitions across the UK:

In Scotland: supports the delivery of *Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision*[8]*, Health and Social Care Delivery Plan 2016*[9] and *Realising Realistic Medicine 2015/16*[10]

In Wales: supports the achievement of ambitions set out in *Taking Wales Forward 2016-2021*[11], *Prosperity for All: the national strategy*[12] and *A Healthier Wales: our Plan for Health and Social Care*[13]

In Northern Ireland: supports the delivery of *Health and Wellbeing 2026: Delivering Together*[14] and the *Medicines Optimisation Quality Framework*[15]

2.2 Programme of work

In 2015 NHS England undertook a scoping project to determine the need for prescribing, supply and / or administration of medicines responsibilities to be extended to a number of regulated health professionals. The resultant report indicated the legal mechanism of

[6] NHS England (2014) *Five year forward view*
[7] NHS England (2019) *The NHS long term plan*
[8] NHS Scotland (2011) *Achieving sustainable quality in Scotland's healthcare: a 20:20 vision*
[9] The Scottish Government (2016) *Health and social care delivery plan*
[10] The Scottish Government (2017) *Realising realistic medicine: Chief Medical Officer's annual report 2015-16*
[11] Welsh Government (2016) *Taking Wales forward 2016-2021*
[12] Welsh Government (2017) *Prosperity for all: the national strategy*
[13] Welsh Government (2018) *A healthier Wales: our plan for health and social care*
[14] DoH Northern Ireland (2016) *Health and wellbeing 2026: delivering together*
[15] DoH Northern Ireland (2016) *Medicines Optimisation Quality Framework*

administration, supply or prescribing that best fits the professions considered, and prioritised certain professions based on current NHS priorities.

The CPOMM Programme of work commenced on 1 April 2017 to take forward the identified priorities. A programme board was established to oversee this work (see appendix A) and a working group was also founded to support the development of this work (see appendix A).

We are leading consultations on behalf of the four nations on proposals which include changes to medicines responsibilities for eight regulated 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

All the proposals share the same aim: to make it easier for people to get the medicines they need when they need them, the first time, and avoiding the need for people to see additional health professionals just to receive medicines.

Views are sought on the proposed changes for each of the eight professions separately because of the differences between the professions, any unique characteristics which apply to them and the changes being proposed for them. Furthermore, changes to medicines legislation need to be considered independently for each profession. However, only one consultation guide has been developed for both dental therapists and dental hygienists due to the similarity of the professions, although views will still be sought on these two professions separately.

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

3 Introduction to the clinical scientist profession

3.1 The role of the clinical scientist

Clinical scientists are statutory regulated healthcare professionals. There are currently 6424[16] clinical scientists registered with the Health and Care Professions Council (HCPC) in the UK. The term 'clinical scientist' is a protected title in law, and all clinical scientists, whether working in the NHS, private or voluntary sectors must be registered with the HCPC.

Clinical scientists perform specialist investigations for enabling the diagnosis and management of disease processes. They are often involved in cutting edge science, ground-breaking research and technological innovation, providing expert care and high-quality service to patients, leading to improvements in quality of life. They are fundamental to deciding the definitive diagnosis of a wide range of diseases and use technological advances in order to drive improvements in longer term monitoring of disease. They often advise medical doctors on tests and interpret data using their understanding of disease processes underpinned by broader knowledge and experience within their specialist area of healthcare science.

Clinical scientists have a high level of responsibility in critically evaluating best practice and are often involved in audit, service development, risk management and quality control which may include accreditation assurance systems. They may plan, undertake, order and / or report on a complex range of procedures and / or treatments using appropriate equipment to meet the needs of service users and exercising a professional duty of care at all times. They are often in positions of leadership working with multi-disciplinary teams and may have a significant role in the training and education of others (i.e. patients, carers, public, colleagues, doctors, peers and students).

The profession of clinical scientist can be subdivided into four main areas of practice; physiological sciences, life sciences, bioinformatics, and physical sciences as set by the educational and training programmes led by the National School of Healthcare Science. For the purposes of this consultation guide, further information about the specific disciplines which are registered under the title 'clinical scientist' can be found in appendix B.

Should legislation be amended, all HCPC registered clinical scientists would be eligible to supply and administer medicines using the PGD mechanism. However, PGDs are only appropriate for use where the practitioner clinically assesses the patient and therefore it is intended that only those clinical scientists with patient-facing roles will be using this mechanism to supply and administer medicines to patients. Local organisations would decide whether a PGD is appropriate for use within a clinical service.

3.2 Where clinical scientists work

Clinical scientists work in a variety of settings many of which involve working face-to-face with patients in clinical settings; from sole-workers in community clinics to large multi-disciplinary clinics in acute hospital settings. Clinical scientists also work in schools, charities, private clinics and universities. Most clinical scientists are employed within the NHS.

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

3.3 The professional bodies

Each of the disciplines encompassed by the professional title of clinical scientist has at least one professional body or association representing them; the organisations often have responsibilities that include promoting the profession, representing their members, providing curriculum frameworks, post-registration education and CPD, complementary to the roles of the HCPC. See appendix C for further details.

3.4 Professional regulation

The purpose of professional regulation is to protect the public. All clinical scientists, whether working in the NHS, private or voluntary sectors, must be registered with the HCPC. The HCPC sets the standards that all registrants have to meet in relation to their education, proficiency, conduct, performance, character and health. These are the standards that the HCPC considers necessary for safe, effective practice. Registrants must meet all these standards and meet the standards relevant to their scope of practice to stay registered. They must complete a professional declaration every two years thereafter, to confirm they have continued to practise and continue to meet these standards. Registrants must also ensure that they have appropriate indemnity in place to cover all of their work. This indemnity may be provided through an employer, a professional body or by private arrangement.

3.5 How clinical scientists are trained

The current training programme in England, Northern Ireland, Wales and Scotland for clinical scientists working in the NHS is the Scientist Training Programme (STP)[17]. The STP is a three-year integrated training programme combining academic study leading to the award of a specifically commissioned MSc in Clinical Science and a work based training programme. Completion of both will lead to the award of a Certificate of Completion of the Scientist Training Programme by the National School of Healthcare Science. Graduates are eligible to apply to the Academy for Healthcare Science for a Certificate of Attainment and will then meet the standards of proficiency[18] required of clinical scientists by the HCPC and be eligible to apply to the HCPC for registration as a clinical scientist.

The STP is designed to provide healthcare scientist trainees with strong science-based, patient-centred clinical training in a specialist area of healthcare science. Initial rotational training provides a broad base of knowledge, skills and experience across a group of related similar specialisms reflective of the evolving clinical and scientific changes and requirements, followed by a focus on a single healthcare scientist specialism.

During the first year of training, the *generic knowledge and understanding* learning outcomes for the STP curriculum will require the student to know the basic principles of clinical pharmacology and therapeutics and understand how those relate to patients and the safety of patients referred to services provided by their division/specialism. This will include an introduction to clinical pharmacology and therapeutics which would entail an overview of

[17] National School of Healthcare Science *NHS Scientist Training Programme*

[18] HCPC (2014) *Standards of proficiency: clinical scientists*

the basic principles of pharmacokinetics and of medicines metabolism / excretion and also the basic mechanisms and clinical importance of medicines interactions.

Post-registration programmes of discipline-specific training equip the student with knowledge in diagnostic applications and therapeutic interventions which include pharmacology of medicines in the context of the specific discipline.

3.6 Continuing professional development (CPD)

Once registered, clinical scientists must undertake CPD and demonstrate that they continue to practise both safely and effectively within their scope of practice in order to maintain their registration. For the duration of their career, registrants are required to maintain a continuous, up-to-date and accurate record of their CPD activities, which must demonstrate a mixture of learning activities relevant to current or future practice. Their CPD activities must contribute to both the quality of their practice and service delivery and benefit service users.

When the members of a profession renew their registration, the HCPC audits the CPD activities of 2.5% of registrants chosen at random from that profession. Those registrants who are chosen for audit must submit a CPD profile to show how their CPD meets the minimum standards of the regulator. A failure to submit or complete successfully an audit leads to administrative removal from the register.

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 be able to supply and administer medicines using PGDs. This is because, whilst clinical scientists are able to supply and administer medicines that have been prescribed, usually by doctors (also known as patient specific directions or PSDs), they often need to refer patients to doctors to receive the medicines they need.

Two options have been considered during the development of this proposal.

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
For some patients the scope of the existing legislation works well where a prescriber is always available.

Limitations
Existing arrangements may not best support the needs of patients who need a medicine prescribed because they experience more nausea than expected, for example. The full impact of this option and the limitations of the current mechanism available to clinical scientists are outlined in section 4.2

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 treatment they need without additional appointments or delays to see a prescriber to receive their medicines. Further information about the anticipated benefits can be found in section 4.3.

Limitations
Should legislation be amended, the limitations of the PGD mechanism[19] 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.

In summary, there are two options for consideration in this consultation:

- **Option 1:** no change
- **Option 2**: legislation is amended to enable clinical scientists to supply and administer medicines using PGDs.

[19] NICE (2017) *Patient group directions: medicines practice guideline*

4.2 Limitations of the current use of medicines mechanisms by clinical scientists

4.2.1 Patient specific direction (PSD)

Clinical scientists are currently able to use PSDs to administer or supply medicines. A PSD is a written instruction to supply or administer a medicine to a named patient who has been assessed on an individual basis by the authorised prescriber who then prescribes the medicine[20]. The PSD then enables a clinical scientist to administer or supply the medicine to the patient. Clinical scientists use this mechanism to administer or supply a number of medicines to patients across their scope of practice in a range of clinical settings. Hence, medicines knowledge and administration techniques are included in pre-registration education and supported through CPD. Additionally, clinical scientists are involved with a number of specialist interest groups and networks that actively promote the safer use of medicines.

PSDs are useful in many care settings; they are individually tailored to the needs of a single patient, wide-reaching and can encompass controlled drugs. However, there are certain limitations to their use:

- they require direct input from an independent prescriber
- they can be restrictive when access to a prescriber is problematic or if the service provided is non-prescriber led
- organisations may limit locally who is authorised to supply and / or administer medicines using PSDs

Avoidable delays in patient care occur when clinical scientists are unable to supply or administer appropriate medicines under existing arrangements. This often results in patients needing to wait for another health professional, to receive the medicines required.

4.3 Benefits of the proposal

Although the use of PSDs has improved patient care, the impact of the use of PGDs for the supply and administration of medicines is anticipated to bring many benefits to patients, commissioners and providers.

4.3.1 Provision of best care, first time, in the right place

The proposed use of PGDs by clinical scientists would improve patient outcomes through timely access to medicines for the undertaking of diagnostic testing. Improving access to medicines will enable patients to receive the treatment they need, first time and without the inconvenience of multiple appointments.

4.3.2 Improved outcomes

Medicines are administered to patients by clinical scientists during the undertaking of certain tests as part of the test or to relieve symptoms evoked. The proposed use of PGDs by clinical scientists would improve patient outcomes through ensuring that they receive the right treatment at the right time without delay. Timely access to medicines through the use

[20] Specialist Pharmacy Service (2018) *Questions about patient specific directions*

of PGDs by clinical scientists would help to improve outcomes by avoiding the risks associated with delayed diagnosis and treatment.

As clinical scientists would be supplying or administering medicines in response to clinical tests and in line with the best evidence contained in the PGD, the medicine they supply or administer would be the most clinically effective for the condition.

4.3.3 Clearer lines of clinical responsibility and accountability

When undertaking some diagnostic investigations such as sleep electroencephalograms (EEGs) and in certain therapeutic interventions, such as response to short-acting bronchodilators in patients with airflow obstruction, clinical scientists are often placed in a position of advising an independent prescriber such as a junior doctor or GP who may not be familiar with the patient's case regarding the prescribing of particular medications to allow the necessary test(s) and treatment to be carried out. Such prescribing practice was highlighted as a concern within the 1999 Crown report[21] and more recently by the General Medical Council[22]. The proposed use of PGDs would enable clinical scientists to take responsibility for decisions to administer or supply medications and ensure clearer lines of responsibility and accountability.

4.3.4 Reduced resource usage and cost effectiveness

In addition to improving patient outcomes and their experience of care, the proposed use of PGDs by clinical scientists also has the potential to improve cost-effectiveness by ensuring the clinical science workforce is effectively utilised. Enabling clinical scientists to supply or administer medicines through the use of PGDs could free up capacity for other health professionals such as GPs and consultants in secondary care. GPs and other health professionals could then use this time to see patients with more complex presentations. Effective use of the workforce is essential in meeting the aims of the *Five Year Forward View*[23] by enabling improvements in health and wellbeing, reducing duplication and fragmentation of care, and making best use of the resources available.

4.3.5 Medicines optimisation

Medicines optimisation looks at how patients use medicines over a period of time. It may involve stopping some medicines as well as starting others and considers opportunities for lifestyle changes and non-medical therapies to reduce the need for medicines. The proposed use of PGDs by clinical scientists could enable patients to get the best use of their medicines in line with the principles of medicines optimisation[24]:

- PGDs must contain information and directions to the health professional administering or supplying the medicine, such as any onward referral or follow up actions to be taken[25].
- PGDs are written and authorised by multidisciplinary groups of health professionals including doctors and pharmacists and should be evidence-based.
- They must be reviewed every two to three years as a minimum and in a timely way following the publication of any new NICE guidance regarding the management of infections.

---

[21] Department of Health (1999) *Review of prescribing, supply and administration of medicines- final report* (Crown report)
[22] General Medical Council (2012) *Investigating the prevalence and causes of prescribing errors in general practice*
[23] NHS England (2014) *Five year forward view*
[24] Royal Pharmaceutical Society (2013) *Medicines Optimisation: Helping patients to make the most of medicines- good practice guidance for healthcare professionals in England*
[25] Human Medicines Regulations 2012

- They should be discontinued if no longer clinically relevant therefore preventing the medicine being used.

4.4 Use in clinical practice

The scenarios below demonstrate how clinical scientists might use PGDs to administer or supply medicines within clinical practice and the benefits to be gained from this proposal. These are only illustrative examples; decisions about the medicines included in PGDs will be for local agreement.

Scenario 1: dexamethasone and neomycin spray

Inflammation of the ear canal may be found during an audiology consultation, particularly after ear wax is removed to allow a better view of the ear canal. Approximately 10% of people will experience this type of inflammation during their lifetime, and it is most commonly diagnosed in those aged 45 to 75[26]. Most cases are caused by bacterial infection, but infection with a fungus, allergy, and irritation may also be involved. In some cases, inflammation will clear up by itself without treatment, but this can take several weeks, causing pain and discomfort in the meantime. An alternative is to apply a local medicine to the ear canal (ear drops or a spray). An example would be dexamethasone and neomycin spray which will typically clear inflammation of the ear canal in a few days[27].

Where hearing loss is a problem, or the patient has additional problems such as learning difficulties, prompt treatment is important in order to facilitate management of the hearing loss and ensure good communication. Currently, patients are required to visit their GP for treatment of ear canal inflammation. In some areas in Wales, clinical scientists work within local audiology services and are the first point of contact for people with ear and balance problems. They will see a number of people with inflammation of the ear canal and will often be the first to identify this condition.

If the clinical scientist in audiology were able to supply treatment such as dexamethasone and neomycin spray through the use of a PGD at the first consultation, patients would receive treatment at the earliest opportunity. The clinical scientist has full access to the patient's medical record and the knowledge required to make an informed decision about treatment of the inflammation. This could result in patients being treated more quickly and symptoms resolving sooner. Patient experience would be improved by enabling the clinical scientist to complete the episode of care and not hand over to another health professional. This would reduce any stress and anxiety from having to attend an additional consultation with a GP.

[26] NHS Choices (2015) *Otitis externa* (last accessed 08/09/2017)
[27] Public Health England (2010, updated 2019) *Managing common infections: guidance for primary care*

Scenario 2: tetracosactide

Hormones are chemicals produced by endocrine glands in the body and released into the blood, where they can affect different cells and organs. For example, the adrenal gland produces the hormone cortisol which helps the body to respond to stress. Dynamic function tests involve either increasing (stimulation) or decreasing (suppression) the production of a particular hormone[28]. In general, if too little cortisol is suspected then a stimulation test should be used, whilst if too much cortisol is considered likely, a suppression test is needed. Patients with acute failure of the adrenal gland (an uncommon but life threatening condition) may have low blood sugar or low sodium, dizziness and fainting. If they have more gradual onset they may be feeling generally unwell, with loss of appetite, vomiting, abdominal pain and weight loss, and signs of dehydration including low blood pressure and a fast heart rate. Unusual dark skin colouring may be seen on sun exposed areas and also on the creases in the palms of the hands and the inside of the mouth.

Tetracosactide acts on the adrenal glands in the same way as the natural hormone which stimulates the adrenal gland. This means that if the adrenal glands are healthy, a single dose of tetracosactide will cause the adrenal glands to produce cortisol, and this can be measured in the blood. If there is adrenal gland failure, the level of cortisol in the blood will not rise, or will only rise a little. This test is known as the Short SynACTHen Test.

Using a comprehensive knowledge of anatomy and physiology of the endocrine or hormone system, knowledge about the various tests, and blood sampling and laboratory medicine techniques, clinical scientists in clinical biochemistry often have responsibility for writing and updating investigation protocols working closely with endocrinologists. Therefore, clinical scientists are very familiar with the test, the reason for using it and the importance of accuracy of the test result for the patient's diagnosis.

Currently the Short SynACTHen test is carried out on wards or assessment units by junior medical staff who may not be able to meet the timescales required to obtain an accurate result because of other clinical work. With access to the use of PGDs, clinical scientists in clinical biochemistry would be able to carry out the test, administering the tetracosactide to the patient, collecting the blood samples at the correct time intervals to then provide accurate understanding and report of the results, providing a diagnosis for the endocrinologist. Thus the patient would receive an accurate diagnosis and treatment, avoiding unnecessary delay and associated anxiety induced by unnecessary waiting.

[28] Barth JH, Butler GE, P J Hammond PJ (2001). *Biochemical Investigations in Laboratory Medicine* (324.00) ACB Ventura Publications, 2001. ISBN 0 902429 34 5

Scenario 3: salbutamol

Chronic obstructive pulmonary disease (COPD) is often misdiagnosed as asthma, leading to inappropriate treatment and suboptimal patient outcomes, and asthma in the elderly is frequently confused with COPD[29].

The recommended diagnostic test for assessing lung function and distinguishing between COPD and asthma is spirometry[30], which assesses how the patient responds to an inhaled medication that relaxes the airways (bronchodilator). If a reduction in the speed that the lungs can be emptied is observed during spirometry (airflow obstruction), it is important to assess if the airflow obstruction can be improved by administering a short-acting bronchodilator medicine such as salbutamol.

A respiratory clinical scientist performing spirometry is immediately able to identify if the patient has airflow obstruction; administration of a bronchodilator at that point allows early diagnosis and appropriate ongoing use of medicines by the patient.

If respiratory clinical scientists were able to use PGDs, they would review the patient's medical history, current medication and results of the spirometry investigation to ensure that it was safe to administer a bronchodilator. They would administer an appropriate dose of bronchodilator medication and record this in the patient record and record that a PGD was used. They would assess the patient's response to the medicine and report the result of the assessment to the requesting clinician with a suggested diagnosis and recommendations for future management.

Scenario 4: proxymetacaine and tropicamide

Electrophysiology of vision testing includes a range of investigations performed in local settings. It is usually undertaken by clinical scientists working with neurophysiology departments, or in specialist vision science units. The diagnostic tests are performed to investigate the function of the back of the eye (retina and optic nerve) and involve the application of specialised electrodes onto the surface of patients' eyes, which can be uncomfortable. This discomfort can be prevented by the use of local anaesthetic eye drops (for example proxymetacaine). It may also be helpful to perform some of the investigations after giving eye drops to widen the pupil of the eye (for example, tropicamide) which gives improved results[31].

At present these medicines are prescribed, for example by a consultant neurophysiologist. The availability of appointments for the tests must be limited to when the neurophysiologist is present to prescribe the medicines. If the tests have to be performed when the neurophysiologist is absent and there is no PSD written for the patient, then the medicines cannot be administered. This is not in line with current best practice guidance and significantly limits the sensitivity of the investigations.

The use of PGDs by clinical scientists in neurophysiology would allow them to directly administer eye drops to widen the pupil and topical anaesthesia to the patient as appropriate during the investigation. This would have the following benefits; improved patient comfort and tolerance of the electrodes that contact the eye, improved test results and a better patient outcome, greater choice of appointments and a reduced wait for the investigation, timely access to testing as there is no delay associated in having to wait for medical staff to complete their clinical commitments before prescribing the medication for administration during the investigation, consistent adherence to international guidelines and improved sensitivity and consistency for all investigations.

[29] British Thoracic Society, Scottish Intercollegiate Guidelines Network (2016) *Asthma guidelines*

[30] Primary Care Commissioning (2013). *A guide to performing quality assured diagnostic spirometry.*

[31] McCulloch, D.L. et al. (2015) *ISCEV Standard for full-field clinical electroretinography* Doc Ophthalmol 130: 1.

Scenario 5: agitated sodium chloride solution

An echocardiogram is a type of ultrasound scan used to look at the heart and nearby blood vessels. A small probe is used to send out high-frequency sound waves that create echoes when they bounce off different parts of the heart. The echoes are picked up by the probe and turned into a moving image that is displayed on a monitor. An echocardiogram can help diagnose and monitor certain heart conditions by checking the structure of the heart and surrounding blood vessels, analysing how blood flows through them, and assessing the pumping chambers of the heart. A cardiac clinical scientist will usually carry out the test in a hospital or community clinic.

A small hole between the right and the left sides of the heart is a significant risk factor which could lead to a patient suffering a stroke or mini-stroke (transient ischaemic attack) if a small clot passed through the hole. Identifying small holes is difficult using standard ultrasound techniques. Right heart contrast echocardiography is a safe test that improves accuracy[32] in the diagnosis of a small hole in the heart called a patent foramen ovale (PFO). This is the standard test for the diagnosis of PFO routinely performed in service and research. This involves the injection of a salt water solution (agitated sodium chloride) into a vein in the arm. If this appears in the left side of the heart it suggests the presence of a small hole between the two sides of the heart.

The cardiac clinical scientist obtains and then interprets the echo images and measurements whilst the patient is undergoing the scan. If the cardiac clinical scientist identifies an abnormality such as dilated right-sided chambers of the heart with no obvious cause, or suspects a congenital abnormality, then injecting agitated sodium chloride solution into the patient's arm vein can help provide more detail.

Currently they must arrange for the agitated sodium chloride solution to be prescribed which can lead to delays or even additional appointments. If the cardiac clinical scientist were able to administer the agitated sodium chloride solution using a PGD whilst the patient was still in the room then this would avoid the delays. It would improve the speed at which the patient received a definitive diagnosis, and ensure that best use of resources was made. If access to the procedure was more readily available then it would inevitably lead to more patients being investigated in this way, thereby enabling early intervention and avoidance of further transient ischaemic attacks or stroke.

4.5 Management of potential risks associated with the proposal

Whenever there is an extension of medicines supply, administration and prescribing responsibilities to regulated health professions there will be associated risks. 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 medicines using PGDs. The risks perceived are not unique to clinical scientists; they are the same as those for other professions that use PGDs to supply and administer medicines. As such, they can be mitigated against by the governance and patient safety measures described in section 5. The main potential risks perceived of the proposal, and a summary of the mitigating actions that can be taken are included in table 1 below.

[32] Mulvagh S.L. et al. (2008) *American Society of Echocardiography Consensus Statement on the Clinical Applications of Ultrasonic Contrast Agents in Echocardiography*. J Am Soc Echocardiogr; 21:1179.

Potential risk	Potential solution
Clinical scientists may supply 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.	• Clinical scientists are required to only supply and administer medicines within their scope of practice and competence and the HCPC has the powers to remove individuals from their register if the person falls below the standards required. • NICE guidance strongly recommends training and also makes reference to common local policy/requirements. • Organisations should ensure that clinical scientists have undertaken relevant training prior to using PGDs. • Local governance arrangements for the use of PGDs will include clinical scientists.
PGD authorising bodies in NHS organisations may not approve PGDs to be used by clinical scientists therefore patients seeing the clinical scientists employed by these organisations will not benefit from the proposed change to legislation.	• As part of implementation, NHS England and NHS Improvement and the devolved administrations, together with professional bodies and other key stakeholders, will raise awareness of any changes in legislation, in order to inform local decision-making to promote consistency.
The limitations of the PGD mechanism[33] 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.	• Although there are some limitations to the PGD mechanism, scoping has identified that PGDs are the best fit for the profession currently.
The time taken for development, approval and review of PGDs in order that clinical scientists can administer and supply medicines using the mechanism can be lengthy which may delay the benefits for patients.	• The time saved by removing the necessity for the writing of PSDs for frequently used medicines will provide some balance to this at an organisational level. • Exemplar PGDs could be shared on the PGD website, hosted by the Specialist Pharmacy Service which could be accessed across the UK.
If the legislation is amended to enable clinical scientists to supply and administer medicines using PGDs but not to supply and 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.	• Information could be provided on the Specialist Pharmacy Service website and the training package updated to make the position clear. • Separate profession-specific PGDs would need to be written for services where the same type of care is provided to patients by clinical scientists and other professions who can supply and administer controlled drugs.

Table 1: Potential risks and governance measures already in place to manage them.

[33] NICE (2017) *Patient group directions: medicines practice guideline*

5 Governance and patient safety

The following governance and patient safety measures are already in place in organisations which employ health professions that can use PGDs to supply and administer medicines. Some of the measures are statutory and some are mandated by organisations.

5.1 Safe use of PGDs

The preferred way for patients to receive the medicines they need is for a prescriber to provide care for an individual patient on a one-to-one basis. If there is a prescriber in the care pathway, they should prescribe for the patient.

The National Institute of Clinical Excellence (NICE) provides guidance on the writing, authorising, implementation and use of PGDs[34] [35] and provides 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.

Although the service is commissioned by NHS England, the NHS Specialist Pharmacy Service team is also commissioned by NICE to provide expert pharmaceutical support and guidance relating to all aspects of the use of PGDs by online information and example PGDs[36]. The information offered is publicly available and in line with NICE guidance. It is therefore applicable to England and Wales but may also be applicable to Scotland and Northern Ireland. For detailed information regarding the safe use of PGDs by all eligible health professionals, see appendix D.

5.1.1 Local governance

PGDs are locally written and locally governed. Organisations already have governance arrangements in place for other professions who use PGDs and clinical scientists would be expected to comply with these. Arrangements include:

- involvement in the writing and authorisation
- implementation of PGDs at service level
- expectation and provision of training
- assurance of competence to supply or administer the medicine(s) included in the PGD by the service lead
- oversight of PGDs in the organisation in which staff are using them
- audits of use and impact

5.1.2 Role of Controlled Drugs Accountable Officer (CDAO)

PGDs can be written to include certain controlled drugs for administration by any eligible health profession (see appendix D). All aspects of controlled drugs management are overseen by a CDAO in each organisation who is accountable for the governance where controlled drugs are used. This includes being familiar with the PGDs for controlled drugs, should any be in place in the organisation. The CDAO is usually the chief pharmacist or other senior person in the organisation; the roles and responsibilities and the requirement to

[34] NICE (2017) *Patient group directions: tools and resources*
[35] NICE (2017) *Patient group directions: medicines practice guideline*
[36] Specialist Pharmacy Service website

appoint a CDAO are governed by legislation[37] [38] [39]. The responsibilities of the CDAO include:

- ensuring that the organisation has a controlled drugs policy that includes use of PGDs
- ensuring that the organisation has a set of standard operating procedures covering all aspects of controlled drug handling and use including PGDs
- ensuring that processes for monitoring compliance are in place
- being a member of a local intelligence network which share concerns and oversee management of controlled drugs

Should legislation be amended all clinical scientists who will be administering midazolam using a PGD must know who the local CDAO is and comply with any local monitoring and / or inspection requests that the CDAO may make including the reporting of any incident or issue related to controlled drugs.

5.1.3 Professional accountability

Clinical scientists must ensure they provide evidence-based care within their scope of practice and competence. Should legislation be amended, when using PGDs to supply or administer medicines, they will be professionally accountable for their decisions, including actions and omissions. This also means that, should legislation be changed, even though clinical scientists could supply or administer a medicine legally, they are not obliged to do so and must work within the HCPC *Standards of Conduct, Performance and Ethics*[40] at all times. Clinical scientists must have due regard to patient safety information and should be aware of, change and update their practice accordingly, which may include not using a PGD until it is amended or reviewed in light of the guidance.

5.1.4 Adverse drug reactions, interactions and errors

If an error in supply or administration occurs whilst using PGDs, clinical scientists must take immediate action to manage the effects on the patient, prevent potential side effects to the patient and must report the error as soon as possible according to local protocols. The reporting of errors must be in an open and transparent way, in order that anything learned from the incident is shared as appropriate.

If a patient experiences an adverse reaction to a medication- once the required treatment has been undertaken, this should be recorded in the patient's notes and, if indicated, the Medicines and Healthcare products Regulatory Agency should be notified via the Yellow Card Scheme[41]. Clinical scientists are expected to be able to recognise common side effects and adverse reactions to the medicines they administer, and to know when there is a potential risk of an interaction.

[37] The Controlled Drugs (Supervision of Management and Use) Regulations 2013
[38] The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 (No 3239) (W. 286)
[39] The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009
[40] HCPC (2016) *Standards of Conduct, Performance and Ethics*
[41] MHRA *Yellow Card Scheme*

5.2 Eligibility and training to use PGDs

Should legislation be amended, all HCPC registered clinical scientists would be eligible to supply and administer medicines using the PGD mechanism. However, it would be for local organisations to agree appropriateness for the use of PGDs within a clinical service using the national guidelines[42] and local governance to inform the decision.

Whilst formal accreditation is not mandatory, clinical scientists should be trained in the use of PGDs as strongly advised by NICE and part of good practice in organisational governance and is currently encouraged for all health professionals legally able to use the mechanism (see appendix E). Competency frameworks[43] set out the skills and knowledge expected by those who undertake the writing, reviewing, implementation and use of PGDs and should inform the curriculum for training programmes. Locally written training programmes may be provided by organisations for their own staff, the e-learning package written by the Centre for Postgraduate Pharmacy Education[44] is freely available and endorsed by the Specialist Pharmacy Service (see section 5.1).

5.3 Communication of decisions to supply and administer medicines using PGDs

It is not expected that communication relating to the use of PGDs by clinical scientists would require any changes to the existing processes that they currently follow in relation to the use of PSDs. If able to use PGDs to supply and administer medicines to patients, clinical scientists will have access to comprehensive medical records and will also obtain additional information from the patient and other health professionals as required. This may include current medicines being taken including over-the-counter, previous side effects experienced to any component of the medicine to be supplied or administered, current and past medical history and any other information that may affect the patient's response to the medicine. The clinical scientist must record in the medical record that this information has been scrutinised and that the medicine is suitable for the patient.

Any medicines supplied or administered by clinical scientists must be recorded within the patient's medical notes. Subject to legislative change, if PGDs are used, a statement that the medicine has been supplied or administered using a PGD should also be included within the patient's record. When supplying or administering controlled drugs using PGDs, clinical scientists must follow any recording requirements specific to the scheduling of the medicine.

The medicines administered are predominantly part of the patient's overall diagnostic procedures of which the GP will be informed in line with information governance procedures. However, if any medicines are supplied using PGDs to the patient to take at home then the GP will be informed in line with good information governance procedures. Clinical scientists already do this when using PSDs.

[42] NICE (2017) *Patient group directions: medicines practice guideline*
[43] NICE (2017) *Patient group directions: tools and resources*
[44] Centre for Postgraduate Pharmacy Education *PGD e-learning package*

5.4 Antimicrobial resistance

Where supply or administration of antimicrobial medicines using PGDs is indicated, clinical scientists will be required to work within their scope of practice and the *Antimicrobial Prescribing and Stewardship Competencies*[45] in line with the requirements of antimicrobial stewardship[46], as well as their role in the prevention of infection in order to remove the need for avoidable antimicrobial use[47]. Effective prevention of infection must be part of the everyday practice of clinical scientists as preventing infections helps to reduce the need for antimicrobials. When administering or supplying antimicrobials using PGDs, clinical scientists must work within local antimicrobial guidelines which take into consideration local resistance patterns. Clinical scientists are expected to be familiar with the requirements of their role in antimicrobial stewardship[48] and to use readily available resources including education programmes[49].

PGDs should only be written for those antimicrobial medicines which are included in local formularies and best practice guidelines, and written and authorised by multidisciplinary groups of health professionals[50]. They must be reviewed every three years as a minimum or in a timely way following the publication of any NICE guidance related to the management of infections and should be discontinued if no longer clinically relevant. PGDs must be written with the involvement of a pharmacist and those for antimicrobials should be discussed with a microbiologist and an antimicrobial stewardship pharmacist also. They would advise on aspects such as the decision to include the antimicrobial in a PGD, the conditions it would be used for (which may be fewer than its manufacturers' authorisation indicates), the duration of the course and the criteria of the clinical scientists for whom the PGD is intended. The antimicrobial should be supplied for as short a treatment duration as possible and in line with local antimicrobial policy and guidelines.

5.5 Use of PGDs by private practitioners

The vast majority of clinical scientists are primarily employed within the NHS, although a number of individuals such as audiological scientists undertake work in the private sector. Many clinical scientists who undertake private sector work simultaneously hold a substantive NHS post, but given the diversity of disciplines within the profession, the precise number of individuals within each of these categories is not known.

As HCPC-regulated health professionals, clinical scientists working in private practice are governed and regulated by the same standards as those working in the NHS, and the standard of care expected is the same. Should PGDs be permitted within the clinical setting (see appendix D), PGDs must be written, authorised and implemented in line with all the relevant national and local governance requirements to include the NICE Medicines Practice Guidance[51]. Employers outside the NHS have the same roles and responsibilities as those within the NHS and must implement the same standard of local governance arrangements related to the safe storage, supply and administration of medicines.

[45] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies*
[46] NICE (2015) *Guidance NG 15: antimicrobial stewardship: systems and processes for effective antimicrobial medicine use*
[47] Department of Health (2008) *The Health and Social Care Act: Code of Practice on the prevention and control of infections and related guidance*
[48] Public Health England (2015) *Antimicrobial stewardship: Start smart - then focus*
[49] Health Education England (2017) *Antimicrobial resistance- a training resources guide*
[50] NICE (2017) *Patient group directions: medicines practice guideline*
[51] NICE (2017) *Patient group directions: medicines practice guideline*

In addition, their practice or clinic must also be registered and regulated by one of the following, depending on the location of the practice:

- in England, the Care Quality Commission - the independent regulator of health and adult social care service providers in England
- in Wales, Healthcare Inspectorate Wales - the independent inspectorate and regulator of healthcare in Wales
- in Northern Ireland, the Regulation and Quality Improvement Authority - responsible for inspecting the availability and quality of health and social care services
- in Scotland, Care Inspectorate Scotland – responsible for regulating independent healthcare services.

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 is required 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 within England, Scotland and Wales have legal obligation under the Equality Act 2010[52], and are required to have due regard to the aims of the Public Sector Equality Duty[53] (PSED) set out at section 149 of the Equality Act 2010, in exercising their functions, such as when making decisions.

There are three aims to the PSED and public bodies must, in exercising their functions, have due regard to them all. They are the need to:

- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010
- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it
- foster good relations between persons who share a relevant protected characteristic and persons who do not share it

The PSED covers the following protected characteristics:

- age
- disability
- gender reassignment
- pregnancy and maternity
- race (includes ethnic or national origins, colour or nationality)
- religion or belief (includes lack of belief)
- sex
- sexual orientation
- marriage and civil partnership (but only in regard to the first aim of the PSED- eliminating discrimination and harassment)

As this is a UK-wide consultation, due regard has also been given to the requirements of section 75(1) of the Northern Ireland Act 1998[54] which requires all public authorities in carrying out their functions relating to Northern Ireland to have due regard to the need to promote equality of opportunity between:

- persons of different religious belief, political opinion, racial group, age, marital status and sexual orientation
- men and women generally

[52] Equality Act 2010
[53] Public Sector Equality Duty 2011
[54] Northern Ireland Act 1998

- persons with a disability and persons without
- persons with dependants and persons without

Furthermore, section 75(2) of the 1998 Act requires public authorities without prejudice to their obligations under subsection (1) to have regard to the desirability of promoting good relations between persons of different religious belief, political opinion and racial group.

6.2 Health inequality duties

Health inequalities have been defined as 'differences in health status or in the distribution of health determinants between different population groups' by the World Health Organisation. The National Health Service Act 2006 as amended by the Health and Social Care Act 2012[55] established specific legal duties on NHS England and NHS Improvement to 'have regard' to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way.

The Act does not define a list of groups impacted by the duties, any group experiencing health inequalities is covered. This means that NHS England and NHS Improvement must consider the whole of the population for which they are responsible, identify inequalities within that population group and have regard to the need to reduce inequalities when exercising their functions.

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.

[55] Health and Social Care Act 2012

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, dentists, doctors, pharmacists, healthcare scientists, allied health professionals, nurses, regulators, the Royal Colleges and other representative bodies.

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 questionnaire

- requesting a paper copy of the consultation response form to be posted to you by contacting: england.cpomedicinesmech@nhs.net or telephone 07733 307316.

  Please complete this form and return it to:

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

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

This consultation remains open for eight weeks and will close on **10th December 2020**.

7.3 Alternative formats

- A patient and public summary version version of this consultation guide is available; it can be made available in alternative formats, such as large print and easy read, and may be available in alternative languages, upon request. Please contact england.cpomedicinesmech@nhs.net

- A paper copy of the patient and public summary consultation guide is available on 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 review, analyse and consider all responses received. A summary of the responses will be published on the NHS England website.

Under the General Data Protection Regulation, NHS England and NHS Improvement will be data controller for any personal data you provide as part of your response to the consultation. NHS England and NHS Improvement have 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. we 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 Ministers, the Medicines and Healthcare products Regulatory Agency (MHRA) will make the necessary amendments. The Human Medicines Regulations are co-signed by the Secretary of State and the Minister of Health in Northern Ireland and 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 and the Misuse of Drugs Regulations could come into force in 2021.

Each nation 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. The resultant focus and pace of this in each respective country are matters for each nation.

8 Appendices

8.1 Appendix A: Contributors

8.1.1 Chief Professions Officers' Medicines Mechanisms Programme Board

Name	Organisation	Organisational Role
Professor Martin Stephens (Chair)	University of Portsmouth/NHS England and NHS Improvement	Visiting professor/Local Pharmacy Network Chair
Suzanne Rastrick (SRO)	NHS England and NHS Improvement	Chief Allied Health Professions Officer
Shelagh Morris (until 30.6.18)	NHS England and NHS Improvement	Deputy Chief Allied Health Professions Officer
Fiona Carragher (until 31.12.18)	NHS England and NHS Improvement	Deputy Chief Scientific Officer
Angela Douglas (from 1.4.19)	NHS England and NHS Improvement	Deputy Chief Scientific Officer
Janet Clarke	NHS England and NHS Improvement	Deputy Chief Dental Officer
Dr Bruce Warner	NHS England and NHS Improvement	Deputy Chief Pharmaceutical Officer
Helen Marriott (until 31.12.18)	NHS England and NHS Improvement	Programme Lead
Dianne Hogg (until 30.9.19)	NHS England and NHS Improvement	Programme Manager (until 13.1.19) Programme Lead (from 14.1.19)
Lois Quayle (from 1.10.19)	NHS England and NHS Improvement	Programme Lead
Claire Potter	Department of Health and Social Care	Medicines Regulation & Prescribing
Graham Prestwich	NHS England and NHS Improvement	Patient & Public Representative
Bill Davidson	NHS England and NHS Improvement	Patient & Public Representative
Anne Ryan	Medicines and Healthcare products Regulatory Agency	Policy Division
Katherine Gough	NHS Dorset CCG	Head of Medicines Management
Dr Joanne Fillingham	NHS Improvement	Clinical Director Allied Health Professions, Deputy Chief AHP Officer
Professor Iain Beith	Council of Deans for Health	Head of a multidisciplinary Health and Social Care School
Graham Mockler	Professional Standards Authority	Head of Accreditation
Samina Malik	Health Education England	Senior Education and Training Policy Manager
Jan Beattie	Scottish Government	Allied Health Professions Officer for Primary Care
Dr Rob Orford	Welsh Government	Chief Scientific Adviser (Health)
Dr Mark Timoney (until 7.12.18)	Northern Ireland Government	Chief Pharmaceutical Officer
Hazel Winning (from 1.1.19 – 1.9.19)	Northern Ireland Government	Lead Allied Health Professions Officer
Steven Sims	NHS England and NHS Improvement	Programme Coordinator
Victoria Ryan (until 11.12.18)	NHS England and NHS Improvement	Programme Administrator

8.1.1 Patient group directions project working group

Name	Organisation	Organisational Role
Fiona Carragher (chair) (until 31.12.18)	NHS England and NHS Improvement	Deputy Chief Scientific Officer
Angela Douglas (chair) (from 1.4.19)	NHS England and NHS Improvement	Deputy Chief Scientific Officer
Shelagh Morris (until 30.6.18)	NHS England and NHS Improvement	Deputy Chief AHP Officer
Thomas Kearney (from 1.12.18)	NHS England and NHS Improvement	Deputy Chief Allied Health Professions Officer
Helen Marriott (until 31.12.18)	NHS England and NHS Improvement	Programme Lead
Dianne Hogg (until 30.9.19)	NHS England and NHS Improvement	Programme Manager (until 13.1.19) Programme Lead (from 14.1.19)
Lois Quayle (from 1.10.19)	NHS England and NHS Improvement	Programme Lead
Karen Stewart	Scottish Government	Healthcare Science Officer
Professor Ian Young	DoH Northern Ireland	Healthcare Science Officer
Dr Rob Orford	NHS Wales	Chief Scientific Adviser (Health)
Tracy Rogers	Specialist Pharmacy Service	PGD specialist advice
Jo Jenkins	Specialist Pharmacy Service	PGD specialist advice
Hannah Abbott	College of Operating Department Practitioners	President
Tracey Williams	The Association for Perioperative Practice	AfPP trustee & vice-president
Dr Jane Needham	Institute of Biomedical Science	Haematology advisor
Denise Cook	Institute of Biomedical Science	Microbiology advisor
Catherine Ross	The Society for Cardiological Science & Technology	President
Dr Jagjit Sethi	British Academy of Audiology	Immediate past president
Manoj Mistry	NHS England and NHS Improvement	Patient & public representative
Ayath Ullah	NHS England and NHS Improvement	Patient & public representative
Steven Sims	NHS England and NHS Improvement	Programme Coordinator

Victoria Ryan (until 11.12.18)	NHS England and NHS Improvement	Programme Administrator

8.2 Appendix B: Overview of clinical science specialisms

8.2.1 Physiological sciences

8.2.1.1 Audiology

Clinical science (audiology) is a patient-facing discipline diagnosing and treating people who are experiencing hearing and balance problems from across the entire life course from new-born through to older adult. Many clinical scientists (audiology) also work with people who have complex conditions and needs such as dementia, mental health conditions, learning disabilities, brain injuries and strokes.

Clinical scientists (audiology) are key members of multidisciplinary teams, working closely with health, social and third sector colleagues, such as ear nose and throat specialists, audio-vestibular physicians, physiotherapists, GPs, school nurses, health visitors and social workers. Assessment and management of audiological conditions requires incorporating a wide range of skills and knowledge base with use of highly specialised equipment. Clinical scientists (audiology) provide care in a wide variety of settings including, acute and community hospitals, patients' homes and some now also work in primary care from GP surgeries. The training provides a strong patient-centred science base in anatomy and physiology, hearing technologies, electrophysiology, acoustics, psychophysics, neurology, vestibular function and assessment, counselling and rehabilitation skills.

Clinical physiology

8.2.1.2 Cardiac physiology

The cardiac physiology workforce operates at the interface of patient and highly specialised cardiac science, technology and innovation. In this patient-facing role the clinical scientist utilises advanced cardiac imaging and rhythm management expertise to diagnose, monitor and manage a range of cardiac disorders such as heart attacks, heart failure, valve disease and stroke. Management of conditions may include the reprogramming of implantable defibrillators to appropriately life threating arrhythmias.

Clinical scientists (cardiology) are mainly based in a hospital secondary care setting. They undertake complex investigations and supervise clinical scientist-led clinics such as valve disease and adult congenital heart disease. The cardiac physiology workforce leads novel research projects that inform clinical practice and work closely within multi-disciplinary teams with consultant cardiologists and surgeons that diagnosis and treat patients in a wide range of patient pathways. They work together with consultant cardiologists and other health professionals in the diagnostic assessment, monitoring and treatment of patients of all ages, from new-born infants to older adults in a wide range of hospital and community settings such as community hospitals, nursing homes, as well as patients' homes, including the operating theatre, critical care and acute medicine.

8.2.1.3 Neurophysiology

Clinical scientists within neurophysiology have a patient-facing role. They measure the function of the peripheral and central nervous system to help in the diagnosis and / or monitor the progress of neurological disorders such as epilepsy, stroke, nerve entrapments, motor neurone disease and multiple sclerosis. Neurophysiology investigations may also be used to monitor function during surgical operations on the brain, spinal cord and peripheral

nerve. Clinical scientists within neurophysiology also have a role in monitoring the progress of disease, and the effects of therapy.

Clinical neurophysiology departments are usually based in hospitals and linked to neurological centres. Most of the investigations in neurophysiology are recorded in dedicated environments, however they may also be performed at the patient's bedside, in the intensive care units, neonatal units and in the operating theatre. A clinical scientist working in this particular area will likely perform a range of highly specialist diagnostic tests using expert theoretical and practical knowledge across their relevant discipline. They are likely to investigate patients of all ages, abilities, all of which requires a considerable amount of patient contact and expert communication skills.

8.2.1.4 Respiratory physiology and sleep

A clinical scientist in respiratory physiology and sleep works directly with patients to diagnose, monitor and manage a range of respiratory and sleep breathing disorders such as chronic obstructive pulmonary disease, interstitial lung disease and obstructive sleep apnoea. They undertake both routine and complex investigations and provide treatments, such as non-invasive ventilation which is used in the management of acute and chronic ventilatory failure based on these results; they are central in novel and translational research, and provide the scientific competences in the procurement, development and testing of new physiologically based methods of diagnosis and treatment. They work together with respiratory and sleep medical consultants and other health professionals to assess and treat patients of all ages, from children with complex asthma to elderly adults who may require home oxygen or assisted ventilation assessment and treatment.

8.2.1.5 Gastro-intestinal physiology

A clinical scientist in gastro-intestinal (GI) physiology works autonomously over a wide range of diagnostic and therapeutic specialities covering the whole of the GI tract from oral to anal cavities. The work entails all aspects of clinical care including triaging referrals; diagnostic analysis and clinical reporting, therapeutics and post therapy counselling, and follow up for patients undergoing tests from three main categories:

- upper GI pressure measurements and ambulatory 24hr pH investigations
- breath tests for helicobacter pylori and gut bacteria
- ano-rectal manometry, ultrasound for cancer staging and bowel re-training

GI physiologists are engaged in all aspects of equipment management: benchmarking equipment performance requirements and calibration: procurement, commissioning and development in conjunction with manufacturers. They are also involved in setting the minimum data set required for the range of diagnostic investigations.

GI physiologists are engaged at all levels of research and development: proposing and contributing to clinical trials; preparing ethics applications; recruiting volunteers and establishing experimental procedures.

8.2.1.6 Ophthalmic and vision science

Clinical scientists in ophthalmic and vision science examine and measure the structure and function of the eye and visual pathways of patients who have ocular or systemic conditions that can cause sight impairment. The role is diagnostic, e.g. specific genetic mutations are signposted by pathognomic visual electrophysiology; the role is also prognostic and involves surveillance of chronic conditions. The clinical scientist in ophthalmic and vision science will be expert in many innovative techniques to assess visual health. They will be specialists in visual electrophysiology and psychophysical techniques that assess function

and use innovative imaging techniques of structure e.g. optical coherence imaging of the retina, ultra-wide retina field imaging, diffusion tensor imaging of the visual pathways in the brain. They will work with patients of all ages and sensory abilities. Scientifically they will be engaged in translation studies to develop therapies and technologies that ameliorate or treat vision threatening conditions.

8.2.1.7 Urodynamics

Urodynamic science is the investigation of urinary-related difficulties. Clinical scientists in urodynamic science, assist in the diagnosis and planning of the treatment for patients with urinary-related conditions. They evaluate patient care pathways relating to common pathological conditions associated with lower urinary tract disorders. They are involved in the diagnosis of lower urinary tract symptoms, including: types of incontinence, voiding problems and associated lower urinary tract symptoms (LUTS). Urodynamic clinical scientists are involved in the research areas relevant to their field of practice and may be based in primary or secondary care setting.

8.2.1.8 Vascular science

Clinical scientists within vascular science work directly with patients and vascular surgeons to diagnose and monitor patients who have a range arterial and venous conditions. These include conditions caused by atherosclerosis such as intermittent claudication, rest pain and tissue loss, as well as strokes, venous disease including varicose veins and deep vein thrombosis. Other conditions include aneurysms and microvascular disease including sickle cell disease. They may work with both adults and children. The nature of many of these conditions can often require urgent intervention or close monitoring. Clinical scientists perform a range of complex diagnostic tests in a range of settings including one stop clinics.

They are a crucial part of the multi-disciplinary team and their assessments have a direct impact on the patient pathway and subsequent treatments. Following treatment clinical scientists will be involved in the monitoring of these interventions for example surveillance of endovascular repair of aortic aneurysms (EVAR) and this may involve the use of a contrast agent. Clinical scientists also lead and contribute to research in a variety of areas including disease processes, imaging techniques, new innovations in technology and equipment solutions within the spectrum of vascular science.

8.2.2 Life sciences

Pathology is the study of disease and includes a number of specialisms in which clinical scientist work to diagnose and manage disease.

8.2.2.1 Clinical biochemistry

Clinical scientists working in these disciplines are based in hospital laboratories and have responsibility for all aspects of laboratory testing and quality, including development and introduction of new tests and the provision of advice to laboratory users about test selection and the interpretation of results. They may also directly interact with patients to perform diagnostic tests or provide information to aid in the understanding of test results.

8.2.2.2 Clinical immunology

The immune system is how all animals, including humans, protect themselves against diseases. Clinical scientists in immunology help to treat diseases like AIDS and cancer, including leukaemia, as well as allergies, such as hay fever, by using complex and sophisticated molecular techniques.

8.2.2.3 Clinical microbiology

This is the study of organisms, including bacterial, viral, fungal and parasitic, that cause infections. A large part of the role of a clinical scientist working in microbiology is the identification and classification of these organisms.

8.2.2.4 Haematology

Including haemostasis and thrombosis, this is the study of the blood and blood-forming tissues. Clinical scientists who work in this area play a major role in the diagnosis and monitoring of patients with disorders of the blood and bone marrow.

8.2.2.5 Histocompatibility and immunogenetics

The main role of a histocompatibility and immunogenetics (H&I) scientist is to provide the services required to support haemopoietic stem cell and organ transplantation programmes. In addition, the H&I scientists support genetic testing for a number of human leukocyte antigens (HLA) and immune-related genes to support disease diagnosis and management, and play a role in the investigation of transfusion-related reactions.

The work involved in the support of transplantation programmes includes HLA typing patients and donors, assessing the closeness of the match and thus helping to select the most appropriate donor for a particular patient. This is crucial to the success of the transplant, as mismatching can result in immune damage to the patient in haemopoietic stem transplantation or rejection in organ transplantation.

8.2.2.6 Genomics

Clinical scientists in genomics are involved in testing patient samples to identify genetic and genomic abnormalities which can result in inherited or acquired (non-inherited) disorders such as cystic fibrosis or cancer. The work falls into 4 main categories:

- prenatal diagnosis – looking for anomalies in the fetus
- carrier testing and risk assessment for identifying pre-symptomatic individuals at risk from single gene disorders
- diagnosis of genetic causes of neurodevelopmental disorders when a specific genetic cause is unknown
- confirmation of diagnosis in both inherited and acquired conditions

Clinical scientists in genomics utilise scientific, technical and clinical knowledge to analyse and interpret the results of routine and complex tests. They write fully interpretative reports for clinicians from a variety of different backgrounds and advise them on investigation strategies. They are provided with opportunities to participate in research and development and the translation of new techniques and assays into routine diagnostic service. Clinical scientists in genomics rarely have direct patient contact however they work as part of a multidisciplinary team which includes Doctors specialising in genomics and other disciplines, genomic counsellors and healthcare science practitioners. In addition to this, scientists liaise with a variety of healthcare professionals and provide expert scientist advice and at all times are aware of the impact of their work on patients.

8.2.2.7 Clinical embryology

This is the study of clinical andrology, embryology fertility treatment and reproductive research. Clinical scientists who work in this area perform diagnostic services and therapeutic andrological and embryological procedures, such as in-vitro fertilisation (IVF), at hospitals and clinics. They are also involved in the collection, storing and fertilisation of sperm and eggs from patients.

Clinical scientists working in reproductive science communicate with patients about specific treatment options regarding fertility, and research infertility solutions with medical, nursing, counselling and administrative colleagues. They have a practical and theoretical understanding of human reproductive biology, andrology and embryology, infertility and assisted reproductive technology (ART) and must keep up to date with current regulations and legislation involving these subjects.

8.2.3 Physical sciences

Clinical scientists in physical sciences develop methods of measuring what is happening in the body, devise new ways of diagnosing and treating disease, and ensure that equipment is functioning safely and effectively. This is a diverse and complex field with roles ranging from research and innovation to direct patient interaction and treatment.

8.2.3.1 Medical physics

Medical physics covers areas such as radiotherapy, radiation safety, imaging with ionising radiation (X-ray, computed tomography (CT), positron-emission tomography (PET), and nuclear medicine) and non-ionising radiation (ultrasound, magnetic resonance (MR), thermography). It could involve commissioning new imaging and therapeutic equipment, advising on safety, working with clinical colleagues to optimise an investigation or treatment, developing new investigations and treatments, reporting on a diagnostic study, or treating a cancer patient by administering a radioactive medicinal product in molecular radiotherapy.

8.2.3.2 Clinical engineering

Clinical engineering brings together engineering principles with biological and medical sciences and includes biomechanics, bioinstrumentation, biomaterials, rehabilitation engineering and clinical engineering. The work may involve the management of medical devices and equipment ensuring that they are functioning correctly and safe to use, the design of innovative equipment for monitoring, diagnosing, treating and rehabilitating patients; the assessment of the individual needs of people with a disability, and in the prescription of assistive technology to meet those identified needs, often whilst working closely with rehabilitation doctors and therapists.

8.2.4 Bioinformatics

Clinical scientist specialising in bioinformatics are responsible for developing and improving methods for acquiring, storing, organising, analysing and interpreting biological data that supports the delivery of patient care. They use areas of computer science including software tools that generate useful biological knowledge by manipulating ‘big data’. All the sub-specialisms of bioinformatics involve working with multi-disciplinary teams in various areas of healthcare.

8.2.4.1 Bioinformatics in genomics

Bioinformatics in genomics involves working with the enormous quantities of data generated by genomic sequencing and coupling this with information about the patient’s physical condition. The focus of the work is in service development which may include designing databases, generating programmes to automate analysis, or creating next generation sequencing pipelines.

8.2.4.2 Bioinformatics in health informatics

Bioinformatics in health informatics involves connecting computing science, information science, biology and medicine. Key activities involve interpretation, integration and reporting from large datasets including various analysis and data-mining techniques and explaining the significance of data findings.

8.2.4.3 Bioinformatics in physical sciences

Bioinformatics in physical science is closely allied to computer science as it involves computer programming, network topologies, ensuring that standards are met and database design. The role primarily involves working with medical equipment and the data they generate.

8.3 Appendix C: professional bodies

Further information about each of the professional bodies can be found on the Academy for Healthcare Science website[56].

Physiological sciences

- British Academy of Audiology
- Society for Cardiological Science and Technology
- Association for Respiratory Technology and Physiology
- Association of Neurophysiological Scientists
- Association of Gastro-Intestinal Physiologists
- British Society for Clinical Electrophysiology of Vision
- United Kingdom Continence Society
- Society of Vascular Technology

Life sciences

- Association for Clinical Biochemistry and Laboratory Medicine
- British Society for Histocompatibility and Immunogenetics
- Association for Clinical Genomic Science
- Association of Biomedical Andrologists
- Association of Clinical Embryologists
- British Fertility Society

Physical sciences

- The Institute of Physics and Engineering in Medicine (IPEM)

Bioinformatics

- The Institute of Physics and Engineering in Medicine (IPEM)
- Association for Clinical Genomic Science
- The British Chartered Institute for IT (BCS)

[56] Academy for Healthcare Science (2018) Clinical science professional bodies

8.4 Appendix D: Best practice use of PGDs

The Human Medicines Regulations require that PGDs are signed by a doctor (or dentist) and a pharmacist, and on behalf of an authorising body. It is good practice that a member of the healthcare profession working under the PGD is also involved in the development of the PGD. The person signing on behalf of the authorising body is often the clinical governance lead who has designated responsibility for signing PGDs on behalf of the authorising body. This responsibility may be delegated by the committee responsible for clinical governance within the organisation. NICE provides guidance on the writing, authorising, implementation and use of PGDs[57].

The legislation also specifies which registered health professionals can use PGDs to supply and administer medicines (Appendix E). Student health professionals are not allowed to work under a PGD unless they are already on the appropriate register; for example, a student health visitor may already be a registered nurse, so would be allowed to work under a PGD.

Healthcare practitioners working under a PGD will need to ensure they have met the training and competency requirements that are detailed in the PGD. They cannot work under a PGD whilst acquiring these skills; for example, a physiotherapist undertaking training in intra-articular injection technique cannot do this under a PGD, unless they have been assessed as competent and authorised to practise by their manager.

A health professional working under a PGD is not permitted to delegate the work to another member of staff under the PGD.

Which medicines can be supplied and / or administered under PGD?

Medicines fall into three legal categories, general sales list, pharmacy medicines, and prescription only medicines. PGDs are necessary to administer or supply prescription only medicines, they are required to supply a pharmacy medicine by authorised health professionals other than pharmacists, but are not needed to administer pharmacy medicines, or administer or supply general sales list medicines.

Where a PGD is not required it is good practice to use a written protocol. Some organisations choose to use a PGD in these situations as they value the rigorous governance arrangements that PGDs offer.

There are five schedules of controlled drugs, some of which can be included under a PGD. Appendix E which lists the professions that are currently eligible to operate under PGDs shows that most of the professions can also use them to supply and administer controlled drugs. Table 2 below gives further details regarding the inclusion of controlled drugs within PGDs.

[57] NICE (2017) *Patient group directions: tools and resources*

Schedule	Examples of controlled drugs	Which controlled drug can a PGD be used for?
Schedule 1	No therapeutic use e.g. LSD and you need a licence to produce, possess or supply	None
Schedule 2	Includes diamorphine, morphine, amphetamines, ketamine	Ketamine, by all eligible staff groups. Morphine and diamorphine in specific circumstances only by nurses and pharmacists
Schedule 3	Includes minor stimulants and other controlled drugs (such as buprenorphine, temazepam, midazolam)	Only midazolam, by all eligible staff groups
Schedule 4	Includes most of the benzodiazepines (except temazepam and midazolam) plus non-benzodiazepine hypnotics. Anabolic steroids and growth hormones	All controlled drugs except anabolic steroids and injectables used for treating addiction
Schedule 5	Certain controlled drugs (such as codeine, pholcodine and morphine) that are exempt from full control when present in medicinal products of specifically low strengths	All controlled drugs

Table 2: the inclusion of controlled drugs within PGDs

Restrictions to what can be supplied/administered under a PGD

- Abortifacients and radiopharmaceuticals cannot be administered under PGD.
- Unlicensed medicines (medicines that do not have a UK marketing authorisation) cannot be given under PGD. This includes medicines that are specially prepared for a patient, sometimes called “specials”.
- Off-label or off-licence is defined as a medicine being used outside of the terms of its UK marketing authorisation (license), such as outside defined indications, doses or routes of administration. For example, when amitriptyline, which is licensed for the treatment of depression, is used for neuropathic pain. As long as this is clearly justified by best clinical practice it would be allowed under a PGD.
- Mixing one medicine with another will usually result in a new unlicensed product being created, unless one product can be described as a vehicle for the administration of the other e.g. as a reconstitution or diluting agent. An example is when ipratropium nebulising solution is mixed with salbutamol nebulising solution prior to administration, making a new unlicensed product; this cannot be administered under a PGD.
- Antimicrobials can be used in PGDs but only when it is clinically essential and clearly justified by best practice guidance, has been agreed by a local specialist in microbiology and their use is monitored and reviewed regularly (see section 5.4).
- Dressings and appliances cannot be supplied or administered under PGD as they are not medicines.

Clinical scenarios that PGDs should not be used in

NICE guidance states that PGDs should not be used in these clinical situations:

- when a medicine needs frequent dosage adjustments or frequent or complex monitoring in a PGD (for example, anticoagulants or insulin)
- when dose adjustments are required to a medicine supplied under a PGD when the medicine is already in the patient's possession
- management of long-term conditions, such as hypertension or diabetes
- when uncertainty remains about the differential diagnosis

Further considerations

- The medicine will need to be available at the time of supply or administration. When the medicine is supplied to the patient to take away then the medicine must be appropriately packaged and labelled. All medicines need to be suitably stored in medicine cupboards or medicine refrigerators which meet the safe storage requirements.
- Where medicines are supplied to a patient to take away there is a requirement to levy a prescription charge where applicable unless the medicine does not require a fee to be charged (e.g. contraceptives, treatment of STI or TB) or the patient is exempt. For convenience, some NHS organisations have introduced systems that avoid health professionals collecting the charges themselves. Examples include arranging for finance departments to invoice patients following treatment and installing pay machines which issue tokens with which patients pay their prescription charges.
- If an exemption exists in the Human Medicines Regulations that allow the drug to be administered or supplied this mechanism should be used instead of a PGD. For example adrenaline injection for anaphylaxis is exempt and a local protocol would be the preferred option.
- The authorisation of PGDs by independent healthcare providers is related to the services in which they are used, not the setting. Private services that are required to be registered with the Care Quality Commission in England, the Healthcare Inspectorate in Wales, the Care Inspectorate in Scotland, or the Regulation and Quality Improvement Authority in Northern Ireland are able to authorise PGDs to be used by that service. If the service provided by the independent provider does not require registration then a PGD cannot be used. If the service is commissioned by the NHS/public health the PGD must be authorised by the commissioner in addition to the provider. All NHS services including those purchased from independent providers must adhere to NICE guidance[58]. Clinical scientists working in an appropriately registered service within an independent provider must ensure that the same level of governance is in place in the organisation before PGDs are used.
- PGDs are not transferrable from one organisation to another; this means that a clinical scientist who works across two organisations cannot use the same PGD in both organisations unless both have authorised the PGD.

[58] NICE (2013) *Patient group directions: medicines practice guideline*

8.5 Appendix E: Registered health professions legally able to use PGDs

Profession	Date commenced using PGDs	Able use PGDs to supply and administer the controlled drugs listed in table 2
Dental hygienists	2010	
Dental therapists	2010	
Dietitians	2003	
Midwives	2000	√
Nurses	2000	√
Occupational therapists	2003	√
Optometrists	2000	√
Orthoptists	2000	√
Paramedics	2000	√
Pharmacists	2000	√
Physiotherapists	2000	√
Podiatrists/chiropodists	2000	√
Prosthetists and orthotists	2003	√
Radiographers - diagnostic	2000	√
Radiographers - therapeutic	2000	√
Speech & language therapists	2003	

8.6 Appendix F: Frequently asked questions.

1) Why is the use of PGDs proposed for clinical scientists?

The proposed use of PGDs by clinical scientists has the potential to improve patient safety by reducing delays in care, improving compliance with medicines; improving patient experience through increased access, convenience, choice and productivity within multi-disciplinary teams. and supporting clearer lines of professional responsibility. The creation of innovative new care pathways would be supported, resulting in improved outcomes for patients especially in a time where there is an increasing demand for services.

2) Would all clinical scientists be able to use PGDs?

It is proposed that only clinical scientists who are currently registered to practise by the HCPC and who have an identified clinical need for PGDs within their scope of practice would be able to use PGDs. However, local organisations would decide whether a PGD is appropriate for use within a clinical service, in line with national guidelines and local governance.

3) What training would clinical scientists undertake to be able to use PGDs?

As part of best practice and organisational governance, clinical scientists using PGDs would need to demonstrate their knowledge and competence. NICE[59] strongly recommends that all health professionals who are required to use PGDs undertake training prior to use. Locally provided training or access to a national e-learning programme such as that provided for England by the Centre for Postgraduate Pharmacy Education could fulfil that requirement. Local clinical governance arrangements will need to ensure that clinical scientists working under a PGD have met the training and competency requirements detailed within the PGD.

4) What assurances are there that it would be safe to enable clinical scientists to supply and administer medicines using PGDs?

Patient safety remains of paramount importance. All PGDs that are written for clinical scientists to use would have patient safety as their primary concern. If changes to legislation occur, clinical scientists would be expected to meet the requirements of the competency frameworks[60] before using PGDs. Clinical scientists using PGDs would be professionally responsible for their own actions; they are required to work within their employers' clinical governance frameworks and are accountable for their actions to both their employers and regulatory body. Once trained, individuals would be required to keep their skills up to date.

5) Will clinical scientists be able to supply and administer medicines to children using PGDs?

It is proposed that clinical scientists using PGDs would be able to supply and administer medicines for children within their paediatric scope of practice and competence. Clinical scientists have experience in supply and administration of medicines for children via PSDs. In addition, local and national policies and procedures would be followed which address medicine management issues in paediatrics.

6) What assurances are there that the proposed use of PGDs by clinical scientists will not increase antimicrobial resistance?

[59] NICE (2017) *Patient group directions: medicines practice guideline*

[60] NICE (2017) *Patient group directions: tools and resources*

Clinical scientists who would be authorised to administer or supply antibiotics using PGDs must be familiar with the requirements of their role in promoting the appropriate use of these medicines (antimicrobial stewardship) and to use readily available resources including education programmes. They would be required to work within their scope of practice *Antimicrobial Prescribing and Stewardship Competencies*[61]. They would also be required to follow local policies for antimicrobial use.

7) What assurances are there that the proposed use of PGDs by clinical scientists will not contribute to oversupply of medication?

Clinical scientists are professionally responsible for ensuring that they adhere to national and local standards of supply and administration of all medicines. Medicines supply is not an activity that occurs in isolation, so it is proposed that clinical scientists using PGDs would communicate with other practitioners involved in the care of patients in order to ensure that medicines supply is not duplicated and is appropriate for the condition to be treated.

8) Would there be an increase in the use of medicines with increased associated costs to the system?

It is proposed that the majority of the medicines that clinical scientists would supply and administer using PGDs will be those that would otherwise be prescribed for their patients. As additional appointments and intervention by other health professionals just to administer or supply a medicine will be prevented, it is expected that costs to the system would fall.

9) How will clinical scientists using PGDs maintain their competence in the proposed use of medicines?

Clinical scientists are required to undertake CPD relevant to their practice to maintain and demonstrate continuing competence. To maintain registration with the HCPC, clinical scientists must sign a professional declaration once every two years to confirm that they continue to meet the HCPC's standards of proficiency for safe and effective practice, and that they meet the HCPC's standards for CPD.

Examples of CPD for clinical scientists include:

- Peer review
- Peer supervising and teaching
- Attending regular meetings
- Attending relevant study days
- Recording self-reflection
- Presenting at conferences
- Membership of relevant special interest groups

Clinical scientists working within the NHS also require annual appraisals, of which medicines management will be a part.

10)Will clinical scientists working outside the NHS be able to use PGDs?

Yes, provided that the PGD is authorised in the organisation and that they are written, authorised and implemented in line with the governance requirements of the NICE Medicines Practice Guidance[62]. See section 5.5 for further information

[61] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies*

[62] NICE (2017) *Patient group directions: medicines practice guideline*

9 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 ministers 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.
Controlled drugs:	Controlled drugs are medicines that are classified in the UK-wide Misuse of Drugs Act 1971 based on their benefit when used in medical treatment and their harm if misused. Strict legal controls apply to controlled drugs to prevent them being misused, being obtained illegally or causing harm. The measures include how controlled drugs can be stored, administered, supplied and recorded.
Controlled Drugs Accountable Officer (CDAO):	Person responsible for all aspects of controlled drugs management within their organisation. The roles and responsibilities of CDAOs, and the requirement to appoint them, are governed by legislation[63] [64] [65].
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 practice in the UK

[63] The Controlled Drugs (Supervision of Management and Use) Regulations 2013
[64] The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 (No 3239) (W. 286)
[65] The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

Term	Explanation
	and is responsible for setting the standards of education, proficiency, conduct, performance, character and health for these professionals.
Human Medicines Regulations 2012:	Set out a comprehensive process for the authorisation of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance. They also set out which health professionals can prescribe medicines, and which can use PGDs and exemptions to supply and administer medicines.
Independent prescriber:	A practitioner responsible and accountable for the assessment of patients with undiagnosed and diagnosed conditions and for decisions about clinical management, including the prescribing of medicines.
Licensed medicines:	A medicine must be granted a licence by the appropriate body before it can be widely used in the UK. A licence indicates all the proper checks have been carried out and the product works for the purpose it is intended for.
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.
Misuse of Drugs Regulations (MDR) 2001	Allow for the lawful possession and supply of controlled (illegal) drugs for legitimate purposes. They cover prescribing, administering, safe custody, dispensing, record keeping, destruction and disposal of controlled drugs to prevent diversion for misuse.
Mixing of medicines:	The combination of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient, where one is not the diluent of the other.
Patient Group Direction (PGD):	A written instruction for medicines to be supplied and / or administered by groups of health professionals to certain groups of patients. They contain information as to which health professionals can supply or administer the medicine, which patients they can see, and when they should involve a doctor or dentist.

Term	Explanation
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.
Prescription Only Medicine (POM):	A medicine that is generally subject to the requirement of a prescription written by an appropriate practitioner (prescriber) before it can be administered or supplied to a patient. There are several exemptions that allow POMs to be administered or supplied without a prescription, including PGDs and exemptions listed in legislation.
Supply of medicines:	The activities undertaken, in response to formal orders, when medicines are issued to the place where they will be used, or supplied directly to the patient.
Unlicensed medicines:	Medicines that are used outside the terms of their UK licence or which have no licence for use in the UK. Unlicensed medicines are commonly used in some areas of medicine such as in paediatrics, psychiatry and palliative care.

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.

A patient and public summary of this consultation guide is available.