



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

October 2020

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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

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1 Introduction to the consultation

1.1 What are we consulting on?

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

Biomedical 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. Biomedical scientists do not often do this, as the tests they are undertaking form part of the assessment process.

This UK-wide consultation is being led by us on behalf of the four nations and relates to the proposal to enable biomedical 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 direction¹. PGDs are a supply or administration mechanism and are NOT a form of prescribing. Further detail about the mechanism can be found in [appendices C & 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 biomedical scientists

The proposed changes require amendment to both the Human Medicines Regulations 2001 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 biomedical 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 biomedical scientists to supply and administer medicines would bring many benefits to both patients and the wider system.

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

- The biomedical scientist scope of practice has increased significantly over the past 10 years with a number now undertaking responsibilities previously only performed by medically qualified pathologists.
- Some biomedical 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 currently may 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 biomedical scientists and advances in biomedical science practice.

Further information about the benefits of this proposal can be found 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 Institute of Biomedical Science, the professional body that represents biomedical scientists in the UK, has also 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. Biomedical scientists would be expected to comply with these resources 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 *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.

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](#)

1.5 The questions being asked

Question 1

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

Question 2

Should amendments to legislation be made to enable biomedical 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 biomedical 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 biomedical 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 stakeholder 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 View⁶ sets 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 Plan⁷ 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 2016 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](#)

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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, and avoiding the need 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 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 biomedical science profession

3.1 The role of the biomedical scientist

Biomedical scientists are statutory regulated healthcare professionals. There are currently 23,367¹⁶ biomedical scientists registered with the Health and Care Professions Council (HCPC) in the UK. The term 'biomedical scientist' is a protected title in law, and all biomedical scientists, whether working in the NHS, private or voluntary sectors must be registered with the HCPC.

In the broadest terms, biomedical scientists produce clinically useful and significant information from analysing tissue and body fluids and providing expert interpretation of test results. They are integral to patient care and well-being in supporting their immediate clinical team decisions regarding diagnosis, treatment and prognosis. Biomedical scientists and their teams analyse over 150 million samples every year, over 70% of all medical diagnoses are made by biomedical laboratory tests.

Their scope of scientific and clinical practice will involve some or all aspects of the diagnosis, treatment, monitoring, screening or research of disease and disease processes. Traditionally, the biomedical sciences fell into the four disciplines of histopathology, medical microbiology, clinical chemistry and haematology but more recently, as advances have been made in diagnostic detection and understanding of disease, these traditional disciplines are merging and working closer together to improve the quality of information.

Although a great deal of work is carried out in the laboratory, biomedical scientists are increasingly being involved as part of multi-disciplinary teams working face-to-face with patients in clinical settings, applying their diagnostic and clinical knowledge and providing expert interpretation of test results. Their input, in these settings, is particularly valuable in the management of haemoglobinopathies (disorders of haemoglobin, such as sickle cell anaemia or thalassaemia), anticoagulant monitoring and investigation of bleeding disorders. In each of these settings, biomedical scientists have their own clinical caseload and assess the test results in the context of the patient's symptoms and known medical conditions, providing an on-site diagnostic service. Their expert knowledge is utilised in the understanding of the relevant disease processes and appropriate escalation of test findings, and in the recommendations made to be actioned by the clinical teams.

3.2 Where biomedical scientists work

Most biomedical scientists are employed within the NHS working in diagnostic laboratories, but increasingly, biomedical scientists are being employed in specialised research laboratories allied to the diagnostic laboratories as well as in the commercial sector, and as sole-workers in community clinics or as part of multi-disciplinary teams working face-to-face with patients in clinical settings. They may also work at the scientific / clinical interface in warfare and humanitarian situations within the armed forces, and in schools, charities, and universities.

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

3.3 The professional body

The Institute of Biomedical Science is the professional body representing biomedical scientists in England, Scotland, Wales, Northern Ireland and the Channel Islands. The role of the professional body is summarised in [appendix B](#) for information.

3.4 Professional regulation

The purpose of professional regulation is to protect the public. All biomedical scientists, whether working in the NHS, private or voluntary sectors, must be registered with the HCPC. The HCPC sets the standards that all registrants must meet in relation to their education, proficiency, conduct, performance, character and health. These are the standards that the HCPC considers 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 biomedical scientists are trained

There are a number of ways to gain entry onto the HCPC register as a biomedical scientist, the usual route is gaining graduate entry by successfully undertaking an IBMS accredited and HCPC approved degree programme¹⁷. There are currently more than 50 universities in the UK offering approved undergraduate courses in biomedical science, via a number of routes including full-time (standard and applied), part-time and sandwich. As part of the academic award, a trainee biomedical scientist also undertakes practical experience as either a placement or by employment within a laboratory. This experience is fundamental to the achievement of competence in biomedical science, satisfaction of these criteria allows the trainee biomedical scientist to apply for entry to the HCPC register.

Nationally, the newest route to becoming a biomedical scientist is to join the Practitioner Training Programme¹⁸, led by Health Education England which developed from the *Modernising Scientific Careers* programme¹⁹. Currently, there are 11 universities in the UK offering over 22 accredited bachelor honours degree programmes in life sciences. Like IBMS-accredited degrees, the programme is an undergraduate training scheme that includes work-based and academic learning. The first year of the programme covers a broad range of scientific training and in the second and third year students specialise in a field of their choice from the range offered by the education provider. On graduation, students will be qualified biomedical science practitioners and will be eligible for professional registration with the HCPC as biomedical scientists.

The course curriculum includes the importance of medicine actions in the living organism for prevention and treatment of disease, the principles of medicine-receptor interactions and the relationship between dose and response, routes of administration, types of medicines,

¹⁷ HCPC (2014) [Standards of proficiency: biomedical scientists](#)

¹⁸ National School of Healthcare Excellence [NHS Practitioner Training Programme](#)

¹⁹ UK Health Departments (2010) [Modernising scientific careers the UK: way forward](#)

how medicines are metabolised and eliminated from the body, toxic effects, medicine discovery and personalised medicine.

3.6 Continuing professional development (CPD)

Once registered, a biomedical scientist follows a career pathway which involves undertaking the IBMS specialist diploma in their chosen biomedical science discipline such as blood sciences or microbiology and can lead to them becoming a specialist biomedical scientist. They work autonomously at this level displaying high levels of confident decision-making. Further development can be achieved by undertaking higher level professional qualifications (also offered by the IBMS) such as the Higher Specialist Diplomas, Advanced Specialist Diplomas, the Certificates of Expert Practice and Diplomas of Expert Practice.

For the duration of their career, biomedical scientists are expected to undertake CPD to ensure that they are practising at the forefront of the profession in terms of competency, quality and currency. The expectation is that they take responsibility to identify any developmental needs and respond to them.

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 biomedical scientists to be able to supply and administer medicines using PGDs. This is because, whilst biomedical 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; biomedical scientists would continue to use PSDs to supply and administer medicines to their patients.

Benefits

For a few 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 the majority of patients that biomedical scientists see, who need a medicine prescribed because of the results of the test they have taken part in. The full impact of this option and the limitations of the current mechanism available to biomedical scientists are outlined in [section 4.2](#)

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

Benefits

Patients who are treated by biomedical 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 mechanism²⁰ may mean that not all the patients that biomedical 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 biomedical scientists to supply and administer medicines using PGDs.

²⁰ NICE (2017) [Patient group directions: medicines practice guideline](#)

4.2 Limitations of the current use of medicines mechanisms

4.2.1 Patient specific direction (PSD)

Biomedical scientists are currently able to use PSDs to administer or supply a medicine. 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 medicine²¹. Biomedical scientists infrequently use this mechanism to administer medicines to patients; instead they commonly refer patients to doctors to obtain the medicines they need. They advise doctors about medicines based upon the results of diagnostic tests across their scope of practice in a range of clinical settings. Hence, some medicines knowledge is included in pre-registration education and supported through CPD.

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 biomedical 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

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

The proposed use of PGDs by biomedical scientists should enable patients to access the medicines they need for diagnosis or treatment in a timely and effective manner. 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

The results of some tests may indicate prompt treatment which involves the supply of medicines. Currently, the patient has to be assessed by a prescriber, usually a doctor, to receive the medicines they need. If a doctor isn't available at the time of the test this can result in delays in receiving the appropriate treatment. Timely access to medicines through the proposed use of PGDs by biomedical scientists would help avoid the risks associated with delayed diagnosis and treatment.

²¹ Specialist Pharmacy Service (2018) [Questions about patient specific directions](#)

4.3.3 Clearer lines of clinical responsibility and accountability

When undertaking some diagnostic investigations and therapeutic interventions, such as is the case in biomedical scientist-led anticoagulation assessment clinics, biomedical scientists are often placed in a position of advising an independent prescriber 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 report²² and more recently by the General Medical Council²³. The proposed use of PGDs would enable biomedical 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 biomedical scientists also has the potential to improve cost-effectiveness by ensuring the biomedical science workforce is effectively utilised. Enabling biomedical 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 can then use this time to see patients with more complex presentations. Effective utilisation of the workforce is essential in meeting the aims of the *Five Year Forward View*²⁴ by enabling improvements in health and wellbeing, reducing duplication and fragmentation of care, and making best use of the resources available. More recently the NHS Long Term Plan²⁵ and the NHS People Plan²⁶ have restated the need to increase capacity through new roles and new ways of working.

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 biomedical scientists could enable patients to get the best use of their medicines in line with the principles of medicines optimisation²⁷.

- 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 taken²⁸.
- 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.
- They should be discontinued if no longer clinically relevant therefore preventing the medicine being used.

²² Department of Health (1999) [Review of prescribing, supply and administration of medicines- final report](#) (Crown report)

²³ General Medical Council (2012) [Investigating the prevalence and causes of prescribing errors in general practice](#), London

²⁴ NHS England (2014) [Five year forward view](#)

²⁵ NHS England (2019) [The NHS long term plan](#)

²⁶ NHS England (2020) <https://www.england.nhs.uk/ournhspeople/>

²⁷ Royal Pharmaceutical Society (2013) [Medicines Optimisation: Helping patients to make the most of medicines- good practice guidance for healthcare professionals in England](#)

²⁸ [Human Medicines Regulations 2012](#)

4.4 Use in clinical practice

The scenarios below demonstrate how biomedical 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 require local agreement.

In the scenario examples, biomedical scientists are not currently using PSDs routinely as the biomedical scientist is acting on abnormal results and accessing the patient in situations where prescribers are not available or experienced in that aspect of care, therefore the provision of PSDs is often delayed.

Scenario 1: intravenous iron

Transfusion of blood saves many lives in acute trauma and enables the performance of complex surgical procedures which would not be safe for the patient without replacing the blood that has been lost. Blood is kindly donated by people for the care of others in need, however it is a very precious and scarce resource. This scenario involves the “Patient Blood Management²⁹” system; an evidence-based multidisciplinary approach to optimise the care of patients who may require blood transfusion but to reduce the need in those patients for which there is an alternative treatment.

Prior to surgical procedures, routine blood tests are performed which includes measuring haemoglobin level to check if a patient is anaemic; this may be due to blood loss or to another medical condition which is then investigated by the patient’s surgical team if the cause is unknown. Patients may be on a surgical ward or in the emergency department awaiting surgery. Biomedical scientists working as transfusion practitioners are ward-based; they see patients for whom requests for blood transfusion are not consistent with local transfusion protocols, and who may require further laboratory investigations. When further tests indicate iron deficiency as the cause of anaemia, the treatment of choice in line with best practice³⁰ is oral iron therapy or an intravenous infusion of iron if surgery cannot be delayed.

Currently, the biomedical scientist informs the surgical team of the iron deficiency anaemia; the surgical team may then refer to the haematology medical team for advice. The haematology team would discuss the patient with the biomedical scientist transfusion practitioner, and would review the patient and prescribe iron dextran to be administered by intravenous infusion. Due to the time taken, the iron dextran may need to be administered by the nursing staff the next day which may lead to a delay in surgery taking place.

In this scenario, if biomedical scientists were able to use PGDs they would be able to review the test results and following best practice, promptly administer the iron dextran to a patient under the PGD. This would provide prompt treatment and monitoring during the infusion, save both medical and biomedical scientist time, provide parity between the services that biomedical scientists and other transfusion practitioners can provide and prevent duplication of effort. Biomedical scientist transfusion practitioners would require the necessary cannulation, monitoring and recording competencies but it is expected that such skills are standard practice for practitioners who are already able to authorise the transfusion³¹ of blood components with the necessary patient monitoring and actions should a reaction occur. Ultimately it would allow for surgery to be scheduled promptly therefore reducing anxiety to the patient and ensuring the best use of clinical resources.

²⁹ Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (2013) [Handbook of transfusion medicine](#)

³⁰ NICE (2015) NICE guidance (NG24) [Blood transfusion](#)

³¹ Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (2013) [Handbook of transfusion medicine](#)

Scenario 2: Vitamin K- diagnosis

Biomedical scientists form part of multidisciplinary teams providing clinical services for patients with suspected or diagnosed bleeding disorders and may have their own clinic and / or caseload of patients referred by their local GPs and hospital clinicians. The reasons for easy bruising are varied and investigation of the clotting process depends upon presentation of symptoms, medical and dietary history. Tests performed aim to identify if there are reduced amounts of any coagulation factors in the blood which can be inherited or due to dietary factors. Following an initial blood test, a course of oral vitamin K (10 mg daily for 2 weeks) is supplied and the blood tests repeated immediately on completion of the vitamin K course. Timing is crucial to obtain an accurate diagnosis. If the results are normal following vitamin K treatment this confirms that the patient does not have an inherited bleeding disorder and can be given advice on increasing the dietary intake of vitamin K.

Currently, biomedical scientist must ask a consultant haematologist to prescribe the vitamin K but they are often not readily available due to seeing other patients in their own clinics or patients on the wards. An alternative is to write and ask GPs to prescribe vitamin K but that causes significant delay. If biomedical scientists were able to use PGDs, they would be able to discuss the importance of diet and supply a course of vitamin K to appropriate patients based on their test results and medical history. This would also ensure repeat tests were performed at the correct time at the end of the course to support accurate diagnosis, reducing delay and anxiety for patients.

Scenario 3: Vitamin K- treatment

Some people have medical conditions or undergo surgical procedures that put them at increased risk of producing a harmful blood clot (thrombosis). As part of their medical treatment, they may need to take warfarin, an anticoagulant medication which works by slowing down the body's blood clotting process. This helps to reduce the risk of developing a thrombosis³².

Patients taking warfarin need to have their blood clotting monitored regularly as the dose of warfarin required must be tailored to each patient; there is not one standard dose for all patients. A blood test called the International Normalised Ratio (INR) is used to monitor the effectiveness of warfarin therapy. It is equally important to reduce the risk of experiencing bleeding associated with too much anticoagulation effect in the blood. Major bleeding can be life-threatening or life-changing in the case of intracranial (inside the head) bleeding, resulting in death or a debilitating stroke.

Biomedical scientists providing anticoagulant dosing decision support are the first healthcare professionals to be aware of high INRs and thus identify patients at risk of potentially serious bleeding. The use of PSDs is not helpful in this scenario as this is not a treatment planned in advance for a named patient, the biomedical scientist is acting on abnormal results and accessing the patient in situations where prescribers are not available or experienced in that aspect of care. Currently, patients attending biomedical scientist-led anticoagulant services with an identified high INR must see another prescriber, usually a doctor, to be prescribed a single dose of vitamin K to be taken orally. However, if another prescriber is not readily available this can result in delays in commencing treatment. The medicine used is licensed to be given by injection so this use is off label but there is no other alternative and the injection is administered orally as standard practice^{33,34}. Licensed medicines used outside of their licensed indications can be included in PGDs as long as there is robust evidence to support the use³⁵.

³² Holbrook A, Schulman S, Witt DM et al (2012) [Evidence-based management of anticoagulant therapy: antithrombotic therapy and prevention of thrombosis](#), 9th edn: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest; 141 (2 Suppl): e152S–e184S

³³ NICE (2018) British National Formulary (BNF): [Oral anticoagulants](#)

³⁴ Keeling D et al (2011) [Guidelines on oral anticoagulation with warfarin – fourth edition](#) British Journal of Haematology

³⁵ Specialist Pharmacy Service (2018) [Can patients receive medicines under PGD when they are used outside their licensed uses?](#)

The ability of a biomedical scientist to administer a single dose of vitamin K using a PGD to reverse the anticoagulant effect of warfarin, would provide the opportunity for early intervention before the patient experiences symptoms, reducing the risk of a serious bleed and its associated subsequent health complications. Where services are nurse or pharmacist-led, this treatment is currently administered using a PGD or prescribed.

Scenario 4: Varicella zoster immunoglobulin

Chickenpox (varicella zoster virus [VZV] infection) is a common childhood illness but one that can also occur in adults. If the infection is contracted by women in early pregnancy, it can be associated with serious adverse consequences for the baby such as congenital varicella syndrome (which can result in damage to the baby's skin, eyes, legs, arms, brain, bladder or bowel). It can also cause VZV pneumonia and varicella infection, which may lead to severe illness or even death of the mother and baby. Stocks of the varicella zoster immunoglobulin (VZIG) are limited nationwide and are usually kept centrally and supplied on a patient-by-patient basis. Given at the right time, VZIG can make the symptoms of chickenpox much milder, last for a shorter period of time and may also protect the baby from catching the virus. The beneficial effect of VZIG is optimised when given within 72 hours of exposure to the virus.

In cases of possible chickenpox in pregnancy, GPs request an urgent blood test in line with current best evidence^{36 37}. A blood sample is sent to a virology laboratory where a test for antibodies to VZV is carried out by a biomedical scientist. When the test fails to detect antibodies, this indicates that the patient has no immunity to VZV, and therefore immunisation is warranted.

Currently, the biomedical scientist would refer a negative result to a consultant virologist, who would authorise supply of an injection of VZIG to the patient's GP who would administer it. If the consultant virologist is unavailable or cover is being provided by another consultant working at another laboratory some distance away, there could be a delay of several days before the GP can give the patient the VZIG. The use of PSDs is not helpful in this scenario as the biomedical scientist is acting on an urgent negative result where prescribers are not available or experienced in that aspect of care. If the biomedical scientist were able to use PGDs, they would be able to act on the negative antibody result without delay. The patient would attend the hospital where the biomedical scientist would check that they meet the inclusion criteria of the PGD and administer the VZIG. This would prevent unnecessary delays, maximise the efficacy of the VZIG, and alleviate patient anxiety at the earliest possible opportunity.

³⁶ Public Health England (2015) [Immunisation against infectious disease: Varicella](#).

³⁷ Royal College of Obstetricians and Gynaecologists (2015) [Chickenpox in pregnancy](#).

4.5 Management of potential risks of 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 biomedical scientists to supply and administer medicines using PGDs. The risks perceived are not unique to biomedical 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.

Potential unintended consequences	Potential solution
Biomedical 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.	<ul style="list-style-type: none"> • Biomedical scientists are required to only supply and administer medicines within their scope of practice and competence and the HCPC as the regulator 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 biomedical scientists have undertaken relevant training prior to using PGDs. • Local governance arrangements for the use of PGDs will include biomedical scientists.
PGD authorising bodies in NHS organisations may not approve PGDs to be used by biomedical scientists therefore patients seeing the biomedical scientists employed by the organisation will not benefit from the change to legislation.	<ul style="list-style-type: none"> • As part of implementation, NHS England and NHS Improvement and the devolved administrations, together with professional bodies and key stakeholders, will raise awareness of any changes in legislation, in order to inform local decision-making and promote consistency.
The limitations of the PGD mechanism ³⁸ may mean that not all the patients that biomedical scientists see will benefit from the proposed changes to legislation, such as those requiring medicines with variable dosing.	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • The time saved by removing the necessity for the writing of PSDs for

³⁸ NICE (2017) [Patient group directions: medicines practice guideline](#)

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<p>biomedical scientists can administer and supply medicines using the mechanism can be lengthy which may delay the benefits for patients.</p>	<p>frequently used medicines will provide some balance to this at an organisational level.</p> <ul style="list-style-type: none"> • Exemplar PGDs could be shared on the PGD website, hosted by the Specialist Pharmacy Service which could be accessed across the UK.
<p>If the legislation is amended to enable biomedical 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.</p>	<ul style="list-style-type: none"> • 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 biomedical scientists and other professions who can supply and administer controlled drugs.

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

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^{39 40} 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 and NHS Improvement, 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 PGDs⁴¹. 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 C](#).

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 biomedical 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 only certain controlled drugs for administration by any eligible health profession (see [appendix C](#)). 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

³⁹ NICE (2017) [Patient group directions: tools and resources](#)

⁴⁰ NICE (2017) [Patient group directions: medicines practice guideline](#)

⁴¹ Specialist Pharmacy Service [website](#)

requirement to appoint a CDAO are governed by legislation^{42 43 44}. 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 local intelligence networks which share concerns and oversee management of controlled drugs

Should legislation be amended, all biomedical scientists who will be administering controlled drugs using PGDs 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

Biomedical 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 biomedical 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*⁴⁵ at all times. Biomedical 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 when using PGDs, the biomedical scientist must take immediate action to manage the effects to 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 the MHRA should be notified via the Yellow Card Scheme⁴⁶. Biomedical 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.

⁴² [The Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#)

⁴³ [The Controlled Drugs \(Supervision of Management and Use\) \(Wales\) Regulations 2008 \(No 3239 \) \(W. 286\)](#)

⁴⁴ [The Controlled Drugs \(Supervision of Management and Use\) Regulations \(Northern Ireland\) 2009](#)

⁴⁵ HCPC (2016) [Standards of Conduct, Performance and Ethics](#)

⁴⁶ MHRA [Yellow Card Scheme](#)

5.2 Eligibility and training to use PGDs

Should legislation be amended, all HCPC-registered biomedical 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 proposed use of PGDs within a clinical service using the national guidelines⁴⁷ and local governance to inform the decision.

Whilst formal accreditation is not mandatory, biomedical 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 D](#)), Competency frameworks⁴⁸ 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 Education⁴⁹ 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 the communication of the use of PGDs by biomedical 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, biomedical scientists will have access to comprehensive medical records and 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 biomedical 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 biomedical 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, biomedical 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 will be supplied using PGDs to the patient to take at home then the GP will also be informed in line with good information governance procedures.

⁴⁷ NICE (2017) [Patient group directions: medicines practice guideline](#)

⁴⁸ NICE (2017) [Patient group directions: tools and resources](#)

⁴⁹ Centre for Postgraduate Pharmacy Education [PGD e-learning package](#)

5.4 Antimicrobial resistance

Some biomedical scientists already lead or are involved in antimicrobial stewardship teams within organisations, providing feedback to prescribers about antimicrobial use. Where supply or administration of antimicrobial medicines using PGDs is indicated, biomedical scientists will be required to work within their scope of practice and the *Antimicrobial Prescribing and Stewardship Competencies*⁵⁰ in line with the requirements of antimicrobial stewardship⁵¹ as well as their role in the prevention of infection in order to remove the need for avoidable antimicrobial use⁵². Good infection prevention and prudent antimicrobial use are essential to ensure safe and effective care for all. Effective prevention of infection must be part of the everyday practice of biomedical scientists as preventing infections helps to reduce the need for antimicrobials. When administering or supplying antimicrobials using PGDs, biomedical scientists must work within local antimicrobial guidelines which take into consideration local resistance patterns.

Biomedical scientists are expected to be familiar with the requirements of their role in antimicrobial stewardship⁵³ and to use readily available resources including education programmes⁵⁴.

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 professionals⁵⁵. They must be reviewed every three years as a minimum and 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) and the duration of the course. 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 biomedical scientists are primarily employed within the NHS or are employed in the private sector and contracted to provide NHS services.

As HCPC-regulated health professionals, biomedical 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 in the clinical setting (see [appendix D](#)), PGDs must be written, authorised and implemented in line with all the relevant and local governance requirements, including the NICE Medicines Practice Guidance⁵⁶. 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.

⁵⁰ Department of Health and Public Health England (2013) [Antimicrobial prescribing and stewardship competencies](#)

⁵¹ NICE (2015) [Guidance NG 15: antimicrobial stewardship: systems and processes for effective antimicrobial medicine use](#)

⁵² Department of Health (2008) [The Health and Social Care Act: Code of Practice on the prevention and control of infections and related guidance](#)

⁵³ Public Health England (2015) [Antimicrobial stewardship: Start smart - then focus](#)

⁵⁴ Health Education England (2017) [Antimicrobial resistance- a training resources guide](#)

⁵⁵ NICE (2017) [Patient group directions: medicines practice guideline](#)

⁵⁶ NICE (2017) [Patient group directions: medicines practice guideline](#)

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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 2010⁵⁷, and are required to have due regard to the aims of the Public Sector Equality Duty⁵⁸ (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 1998⁵⁹ 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

⁵⁷ [Equality Act 2010](#)

⁵⁸ [Public Sector Equality Duty 2011](#)

⁵⁹ [Northern Ireland Act 1998](#)

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- 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 2012⁶⁰ 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.

⁶⁰ [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, 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

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 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. NHS England and NHS Improvement 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.

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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 (until 30.9.19)	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 (14.1.19 – 30.9.19)
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

8.1.2 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 1.10.18)	NHS England and NHS Improvement	Deputy Chief AHP 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 (14.1.19 – 30.9.19)
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

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Victoria Ryan (until 11.12.18)	NHS England and NHS Improvement	Programme Administrator
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8.2 Appendix B: Role of the professional body

The Institute of Biomedical Science (IBMS) is the UK's professional body for biomedical scientists, laboratory support staff and students. With over 20,000 members in more than 30 countries, the IBMS represents a professional workforce that brings immense benefits to patient care and to the health economy. For over 100 years the IBMS have supported members in their practice, setting quality standards for the profession through training, education, assessments, examinations and continuing professional development.

The IBMS supports the full spectrum of the biomedical science workforce and, alongside the quality assurance and approval by the HCPC, accredits degrees for the purpose of regulation, has a code of conduct and has half of the HCPC-registered biomedical scientist workforce in membership. The IBMS has an established structure of post-registration qualifications that enable members to demonstrate competence and expertise in their clinical and scientific practice.

8.3 Appendix C: Best practice use of PGDs

The Human Medicines Regulations (2012) 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 PGDs⁶¹.

The legislation also specifies which registered health professionals can use PGDs to supply and administer medicines (see appendix D). 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 in a PGD. [Appendix D](#) 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.

⁶¹ NICE (2017) [Patient group directions: tools and resources](#)

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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 and / or 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 in which PGDs should not be used

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 medicine 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 guidance⁶². Biomedical 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 biomedical scientist who works across two organisations cannot use the same PGD in both organisations unless both have authorised the PGD.

⁶² NICE (2013) [Patient group directions: medicines practice guideline](#)

8.4 Appendix D: 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/chiropractors	2000	√
Prosthetists and orthotists	2003	√
Radiographers - diagnostic	2000	√
Radiographers - therapeutic	2000	√
Speech & language therapists	2003	

8.5 Appendix E: Frequently asked questions.

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

The proposed use of PGDs by biomedical scientists would bring many benefits to the patient through timely access to the medicines they need and thereby reduce delays in diagnosis and treatment. This would also improve the patient experience by reducing the number of unnecessary - possible duplicated or additional - appointments.

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

It is proposed that only biomedical scientists who are currently registered to practise by the HCPC and 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 biomedical scientists undertake to be able to use PGDs?

As part of best practice and organisational governance, biomedical scientists using PGDs would need to demonstrate their knowledge and competence. NICE⁶³ 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 governance arrangements will need to ensure that biomedical 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 biomedical scientists to supply and administer medicines using PGDs?

Patient safety remains of paramount importance. All PGDs that would be written for biomedical scientists to use would have patient safety as their primary concern. If changes to legislation occur, biomedical scientists would be expected to meet the requirements of the competency frameworks⁶⁴ before using PGDs. Additionally, biomedical scientists 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) Would biomedical scientists be able to supply and administer medicines to children using PGDs?

It is proposed that biomedical scientists using PGDs would be able to supply and administer medicines to children within their scope of practice and competence. 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 biomedical scientists will not increase antimicrobial resistance?

Biomedical scientists who would be authorised to administer or supply antibiotics 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 and

⁶³ NICE (2017) [Patient group directions: medicines practice guideline](#)

⁶⁴ NICE (2017) [Patient group directions: tools and resources](#)

the *Antimicrobial Prescribing and Stewardship Competencies*⁶⁵. They would also be required to follow local policies for antimicrobial use.

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

Biomedical scientists are professionally responsible for ensuring that they adhere to national and local standards of supply and administration of all medicines. Medicines supply and administration is not an activity that occurs in isolation, so it is proposed that biomedical 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 biomedical scientists will supply and administer using PGDs will be those that would otherwise be prescribed. 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 would biomedical scientists using PGDs maintain their competence in the use of medicines?

Biomedical scientists are required to undertake CPD relevant to their practice to maintain and demonstrate continuing competence. To maintain registration with the HCPC, biomedical 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 biomedical scientists include:

- participation in internal and external quality assurance programmes
- reflective practice
- clinical audit
- formal training courses

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

10) Would biomedical 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 Guidance⁶⁶. See [section 5.5](#) for further information.

⁶⁵ Department of Health and Public Health England (2013) [Antimicrobial prescribing and stewardship competencies](#)

⁶⁶ 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, efficacy 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 ^{67 68 69} .
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.

⁶⁷ [The Controlled Drugs \(Supervision of Management and Use\) Regulations 2013](#)

⁶⁸ [The Controlled Drugs \(Supervision of Management and Use\) \(Wales\) Regulations 2008 \(No 3239\) \(W. 286\)](#)

⁶⁹ [The Controlled Drugs \(Supervision of Management and Use\) Regulations \(Northern Ireland\) 2009](#)

Term	Explanation
Health and Care Professions Council (HCPC):	The regulator of 16 different health and care professions including biomedical scientists. It maintains a register of health and care professionals that are fit to practice in the UK 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.

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Term	Explanation
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.
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 exceptions 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 version of this consultation guide is available.