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Consultation on proposed amendments to the list of controlled drugs that podiatrists can independently prescribe across the United Kingdom

October 2020

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

A patient and public summary version of this consultation guide is also 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 proposals to enable podiatrists to prescribe four additional controlled drugs.

Podiatrists have been able to train as independent prescribers since 2013 and have been able to prescribe from a restricted list of four controlled drugs since 2015 in England Scotland and Wales. Since November 2019, legislative changes permit prescribing of the same controlled drugs in Northern Ireland. Further legislative amendments are being progressed to support prescribing in primary care. Controlled drugs are medicines that have additional controls associated with the prescribing, storage or record keeping because they can be misused for non-treatment purposes. The medicines are listed in five schedules or groups and each has different levels of control (see appendix A).

This UK-wide consultation is being led by NHS England and NHS Improvement on behalf of the four nations and relates to the proposal to enable podiatrist independent prescribers to prescribe four additional controlled drugs in the course of their professional practice, namely:

morphine sulfate	schedule 2 and 5	oral administration
tramadol hydrochloride	schedule 3	oral administration
pregabalin	schedule 3	oral administration
gabapentin	schedule 3	oral administration

There are two options for consideration in this consultation:

Option 1: no change

Option 2: addition of four controlled drugs to the existing list of controlled drugs that podiatrist independent prescribers can currently prescribe

The proposed changes require amendment to both the Human Medicines Regulations 2012 and the Misuse of Drugs Regulations 2001. The Human Medicines Regulations apply UK-wide so subject to the agreement of Ministers, changes to them will apply across the four countries. The Misuse of Drugs Regulations apply only to England, Wales and Scotland; the Misuse of Drugs (Northern Ireland) Regulations 2002 will need to be amended separately and this will be undertaken by the Department of Health in Northern Ireland.

Should legislation be amended, the changes would apply throughout the UK, in any setting in which podiatrists work including the NHS, independent and voluntary sectors.

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

A glossary of terms used in this guide can be found in section 9.

1.2 Why are the proposed changes being considered?

The proposed addition of four controlled drugs to the current list of controlled drugs that podiatrist independent prescribers can already prescribe would:

- improve patient outcomes through timely access to appropriate pain relief as part of their podiatric intervention
- reduce the need for patients to have additional appointments with other health professionals to access medicines required
- provide patients with the right treatment and at the right time
- ensure that patients being treated by podiatrist independent prescribers receive evidence-based pain management in line with the World Health Organisation (WHO) analgesic ladder

Further information on the benefits of this proposal is presented in section 4.4. Potential risks and measures in place to manage the risks can be found in section 4.6.

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 College of Podiatry and the Institute of Chiropodists and Podiatrists, the professional bodies that represent podiatrists in the UK have also collaborated in the development of this consultation guide and the supporting documents that accompany it.

1.4 Supporting documents

The following supporting documents are provided alongside this consultation to inform consideration of the options and questions:

- Practice guidance entitled *Good Practice in Prescribing and Medicines Management for Podiatrists*[1]
- *Outline Curriculum Framework for Education Programmes to Prepare Podiatrists as Independent/Supplementary Prescribers*[2]
- *Consultation Stage Impact Assessment*.

1.4.1 Practice guidance

The practice guidance was first published in 2011 by the College of Podiatry and the Institute of Chiropodists and Podiatrists. The document provides information about the behaviours, actions, knowledge and skills which should underpin the decision-making and actions of podiatrist prescribers. The document has been updated as part of this work.

1.4.2 Outline Curriculum Framework

In collaboration with the professional bodies representing radiographers, physiotherapists, paramedics and dietitians, the College of Podiatry and the Institute of Chiropodists and Podiatrists developed and published the *Outline Curriculum Framework* for education

[1] The College of Podiatry *Good Practice in Prescribing and Medicines Management for Podiatrists*

[2] Allied Health Professions Federation (2018) *Outline curriculum framework for education programmes to prepare: physiotherapists, podiatrists, therapeutic radiographers and paramedics as independent/supplementary prescribers and to prepare: diagnostic radiographers and dietitians as supplementary prescribers*

programmes to prepare practitioners to become prescribers. The document is in line with the *Competency Framework for all Prescribers*[3] and the Health and Care Professions Council (HCPC) *Standards for Prescribing*[4].

If legislation is amended to enable podiatrist independent prescribers to prescribe an additional four controlled drugs then no further changes to education programmes will be required as the HCPC *Standards for Prescribing,* against which the education programmes are approved, do not refer to specific medicines. The *Outline Curriculum Framework* already reflects the considerations necessary for education in preparation for the prescribing of any controlled drugs by podiatrist independent prescribers.

1.4.3 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 *Outline Curriculum Framework* contains evidence of the actual (where available) and estimated costs and benefits associated with the proposal. The consultation is an opportunity to gather additional evidence to further inform the costs, benefits and risks of the proposal.

1.5 The questions being asked

Question 1
Should amendments to legislation be made to enable podiatrist independent prescribers to prescribe additional controlled drugs for their patients?

Question 2
Do you have any additional information on any aspects not already considered as to why the proposal to amend the list of controlled drugs which podiatrists can independently prescribe SHOULD go forward?

Question 3
Do you have any additional information on any aspects not already considered as to why the proposal to amend the list of controlled drugs which podiatrists can independently prescribe SHOULD NOT go forward?

Question 4
To what extent do you agree or disagree with each of the proposed controlled drugs that podiatrist independent prescribers would be able to prescribe for their patients?

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?

[3] Royal Pharmaceutical Society (2016) *A competency framework for all prescribers*
[4] Health and Care Professions Council (2013) *Standards for prescribing*

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

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

2 Background

2.1 Context

The Chief Professions Officers' Medicines Mechanisms (CPOMM) programme is set in the context of the current direction of the NHS which puts patients and the public at the heart of everything we do. The Five Year Forward View[5] 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 Plan[6] 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.

NHS England and NHS Improvement 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*[7]*, Health and Social Care Delivery Plan 2016*[8] and *Realising Realistic Medicine 2015/16*[9]

In Wales: supports the achievement of ambitions set out in *Taking Wales Forward 2016-2021*[10], *Prosperity for All: the national strategy*[11] and *A Healthier Wales: our Plan for Health and Social Care*[12]

In Northern Ireland: supports the delivery of *Health and Wellbeing 2026: Delivering Together*[13] and the *Medicines Optimisation Quality Framework*[14]

2.2 Programme of work

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

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

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

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

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 for people to see additional health professionals just to receive medicines.

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

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

3 Introduction to the podiatrist profession

3.1 The role of the podiatrist

Podiatrists are statutory regulated health professionals. There are currently 13,026[15] podiatrists registered with the Health and Care Professions Council (HCPC) in the UK. The terms 'podiatrist' and 'chiropodist' are protected titles by law. The terms both encompass the same role; throughout this consultation guide the term 'podiatrist' will be used for clarity.

Podiatry pre-registration education is at degree level: level 6 on the Framework of Higher Education Qualifications (FHEQ) and the Scottish Credit and Qualifications Framework (SCQF). Undergraduate programmes are delivered within higher education institutions in the UK. All are approved by the HCPC to provide programmes that enable graduates to obtain registration to practise as a podiatrist.

The role of the podiatrist encompasses a broad scope of practice to assess, diagnose and manage a wide range of local and systemic conditions affecting the lower limb. Podiatrists work in a wide variety of locations such as:

- hospitals
- GP practices
- independent practices
- patients' homes
- nursing homes
- day centres
- schools
- health centres
- occupational health settings including prisons, schools, industry, sports clubs and for the Armed Forces

The College of Podiatry and the Institute of Chiropodists and Podiatrists estimate that around 50% and 82% respectively of their practising members undertake an element of their work in the private sector although those podiatrists working in advanced practice largely work in the NHS or private hospital settings.

After registration, podiatrists can choose to develop their skills and experience in one particular speciality, as well as acquire new skills at a post-graduate level. These experienced and additionally trained podiatrists are known as advanced podiatrist practitioners and their role is in line with the national multi-professional definition of advanced clinical practice and associated framework[16] below:

> *Advanced clinical practice is delivered by experienced, registered health and care practitioners. It is a level of practice characterised by a high degree of autonomy and complex decision making. This is underpinned by a master's level award or equivalent that encompasses the four pillars of clinical practice, leadership and management, education and research, with demonstration of core capabilities and area specific clinical competence.*

[15] Health and Care Professions Council registrants by profession & route & gender September 2020
[16] Health Education England (2017) *Multi-professional framework for advanced clinical practice in England*

> *Advanced clinical practice embodies the ability to manage clinical care in partnership with individuals, families and carers. It includes the analysis and synthesis of complex problems across a range of settings, enabling innovative solutions to enhance people's experience and improve outcomes.*

Prescribing is an advanced clinical practice activity that requires specific postgraduate training but is built upon the underpinning knowledge and competence demonstrated from the point of initial registration and maintained throughout professional practice. All podiatrist independent prescribers are advanced practitioners.

Podiatrists can work in a number of speciality areas, some of which are listed below:

- musculoskeletal conditions
- diabetes care
- general podiatric care
- foot surgery

Podiatrist independent prescribers may not currently be prescribing controlled drugs in all these settings, but this may change in the future.

3.2 The professional bodies

The College of Podiatry and the Institute of Chiropodists and Podiatrists are the professional bodies representing podiatrists in England, Scotland, Wales, Northern Ireland and the Channel Islands. The roles of the professional bodies are summarised in appendix C for information.

3.3 Professional regulation

The purpose of professional regulation is to protect the public. All podiatrists, whether working in the NHS, private or voluntary sectors, must be registered with the HCPC. The HCPC sets the standards that all registrants have to meet in relation to their education, proficiency, conduct, performance, character and health. These are the standards that the HCPC considers necessary for safe effective practice. Registrants must meet all these standards to register 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.

There are additional annotations on the register for podiatrists who are:

- eligible to administer, sell and supply prescription-only medicines using exemptions listed in legislation
- supplementary prescribers
- independent and supplementary prescribers

3.4 How podiatrist independent prescribers are trained

3.4.1 Eligibility to access HCPC approved prescribing programmes

Advanced practitioner podiatrists must gain access to, and successfully complete, a HCPC approved prescribing programme in order to achieve annotation on the HCPC register as a podiatrist independent prescriber. There are 82 independent / supplementary prescribing programmes approved for podiatrists by HCPC in the UK - 65 in England, 12 in Scotland and 5 in Wales. There are no programmes currently available in Northern Ireland.

In line with other allied health professions able to train as prescribers (e.g. physiotherapists, therapeutic radiographers and paramedics), podiatrists must meet the entry criteria as listed in the HCPC *Standards for Prescribing*[17] which are developed further in the *Outline Curriculum Framework*[18] and are listed in appendix D.

3.4.2 HCPC approval of prescribing programmes

Prescribing education programmes are a minimum of 38 days in duration including supervision in clinical practice and are offered as multi-professional programmes. Each programme must be approved by the relevant regulator for each prescribing profession and are approved for podiatrists by the HCPC. The HCPC currently approves independent and supplementary prescribing education programmes against the HCPC *Standards for Prescribing*.

The core content of education programmes is the same for all non-medical prescribers, with profession-specific elements and practice-specific assessments designed to allow profession-specific differentiation where required. Programmes are delivered at level 6 (degree level) or level 7 (master's level). The additional considerations related to the prescribing of controlled drugs are included within the education programmes.

The HCPC *Standards for Prescribing* have two purposes:

- They set out the processes and procedures that an education provider delivering training in prescribing must have in place in order to deliver the training safely and effectively.
- They also set out the knowledge, understanding and skills that a registrant must have when they complete their prescribing training and which they must continue to meet once in practice.

3.4.3 Scope of independent prescribing practice

The HCPC defines scope of practice as the areas in which a registrant has the knowledge, skills and experience necessary to practise safely and effectively[19]. The College of Podiatry and Institute of Chiropodists and Podiatrists have further defined the scope of podiatrist independent prescribing in the following statement. This ensures that prescribing within the scope of podiatry practice is aligned with, and remains within, the boundaries of contemporary professional practice and an individual's scope of competence.

> *"The professional bodies agree that it is necessary to direct those members, who are engaged in the practice of independent prescribing, to ensure that they concern*

[17] Health and Care Professions Council (2013) *Standards for prescribing*
[18] Allied Health Professions Federation (2018) *Outline curriculum framework for education programmes to prepare: physiotherapists, podiatrists, therapeutic radiographers and paramedics as independent/supplementary prescribers and to prepare: diagnostic radiographers and dietitians as supplementary prescribers*
[19] HCPC (2013) *Standards of proficiency- chiropodists / podiatrists*

themselves only with those medicines which are relevant to the treatment of disorders affecting the foot, ankle and associated structures, in line with current practice and consistent with published professional guidance"[20].

3.5 Continuing professional development (CPD)

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

Those podiatrists who are members of the College of Podiatry are also required to meet the standards of clinical practice and the code of conduct, ethics and practice as set by the College of Podiatry. Podiatrists who are members of the Institute of Chiropodists and Podiatrists are similarly obliged to meet the standards of clinical practice and professional ethics required for membership.

When the members of a profession within its remit renew their registration, the HCPC randomly audits the CPD activities of 2.5% of registrants in 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 to meet the standards required leads to administrative removal from the register.

Additional requirements are made of those podiatrists who hold additional annotations on the HCPC register listed above including those who have successfully completed prescribing courses approved by the HCPC, which enable the registrant to practise as a supplementary and/or independent prescriber. Advanced practitioners who are also qualified as prescribers must meet not only the general standards for all registrants, but also the additional standards that only apply to prescribers as outlined in the HCPC *Standards for Prescribing*[21]. At the point of re-registration every two years, when podiatrist prescribers must declare that they remain fit to practise as podiatrists; it is implicit in their declaration that they remain fit to practise as a prescriber as this is part of their scope of practice.

Local governance arrangements expect that podiatrist prescribers demonstrate ongoing CPD in line with the document *A Competency Framework for All Prescribers*[22]. Podiatrist prescribers demonstrate this through the use of personal formularies and at annual professional development review. Those who intend to prescribe controlled drugs will be required to clearly demonstrate the continued ability to do this.

[20] The College of Podiatry (2018) *Good Practice in Prescribing and Medicines Management for Podiatrists*
[21] Health and Care Professions Council (2013) *Standards for prescribing*
[22] Royal Pharmaceutical Society (2016) *A competency framework for all prescribers*

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 increase the number of controlled drugs that podiatrist independent prescribers can currently prescribe. In addition to being able to prescribe any licensed medicine within their scope of practice and competence, podiatrist independent prescribers can currently prescribe four controlled drugs for their patients. Consequently, they must refer patients to other prescribers, usually GPs, to receive the controlled drugs that they are currently not permitted to prescribe, even though they have the knowledge, skills and experience to safely and effectively prescribe them for their patients.

Three options have been considered in relation to extending the number of controlled drugs that podiatrist independent prescribers can prescribe for their patients; however, option 3 was deemed to be unviable and therefore only **options 1 and 2** are being considered as part of this consultation.

Option 1: No change

There would be no change to legislation; podiatrist independent prescribers would continue to prescribe from the current restricted list of four controlled drugs and would continue to refer patients to other prescribers if treatment of their condition required any of the proposed controlled drugs and use of supplementary prescribing is impractical.

Benefits
For some patients, the scope of the existing legislation works well, for example for those patients whose pain is relieved adequately and without adverse effects by the controlled drugs currently available to podiatrist independent prescribers.

Limitations
Existing arrangements may not best support the needs of all patients, particularly those for whom the controlled drugs currently available to podiatrist independent prescribers provide inadequate pain relief or produce intolerable side effects. Those patients who are unable to access the most appropriate controlled drug for management of their pain from the podiatrist independent prescriber would have to continue to visit another health professional, usually a GP, to receive the medicines they require. The existing arrangements result in unnecessary delays for patients, duplication of appointments and possibly prolonged pain. The full impact of this option and the limitations of the current mechanisms available to podiatrists are outlined in section 4.2.

Option 2: addition of further controlled drugs to the list of controlled drugs that podiatrist independent prescribers can already prescribe

Benefits
Podiatrist independent prescribers primarily need to prescribe controlled drugs for the management of pain for their patients. Expansion of the current list to include four controlled drugs commonly prescribed for the management of pain would benefit those patients for whom best clinical evidence indicates that these medicines work most effectively. If legislation is amended, when seeing podiatrist independent prescribers, patients would receive the right treatment at the right time without needing additional appointments with other health professionals just to receive the medicines they need. The rationale for the selection of the four controlled drugs can be found in section 4.3.

Limitations
The proposed additions to the current list of controlled drugs that podiatrist independent prescribers could prescribe may mean that a small number of patients may still need additional appointments with other health professionals to access controlled drugs outside of those that podiatrist independent prescribers are permitted to prescribe. This is most likely to be because they need controlled drugs for a medical condition that is outside of the usual scope of practice of a podiatrist.

Option 3: independent prescribing of any controlled drug from schedules 2 - 5

An option whereby podiatrist independent prescribers would be able to prescribe any controlled drug from schedules 2 - 5 was considered but not deemed a viable option due to governance considerations. This option was therefore not taken further as part of this consultation.

Benefits:
There is only one benefit of this option perceived and that is that this option would prevent the need for any further amendments to the list of controlled drugs that podiatrist independent prescribers can prescribe.

Limitations:
Podiatrist independent prescribers would have access to a large number of controlled drugs listed in the four schedules, in excess of 100 in schedule 2 alone, most of which would not ordinarily need to be prescribed as part of podiatry practice. Access to all controlled drugs within schedules 2-5 is therefore deemed unnecessary and not in line with good governance procedures.

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

Option 1: no change
Option 2: addition of four controlled drugs to the existing restricted list of controlled drugs that podiatrist independent prescribers can already prescribe

4.2 Limitations of the current use of medicines mechanisms by podiatrists

4.2.1 Supply and administration mechanisms

4.2.1.1 Patient specific directions (PSDs)

Podiatrists can administer and supply medicines to named patients using PSDs. A PSD is a written instruction to supply or administer a medicine to a named patient who has been assessed on an individual basis by the authorised prescriber who then prescribes the medicine[23]. The PSD then enables a podiatrist to administer or supply the medicine under certain circumstances.

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

The use of PSDs has inherent limitations to independent practice; for instance, when in remote situations, where a GP may not always be immediately available or where a doctor is not part of the patient pathway.

4.2.1.2 Patient group directions (PGDs)

Since 2000, podiatrists have been able to supply and administer medicines to patients meeting certain criteria using PGDs. PGDs provide a legal framework that allows the supply and administration of a specified medicine(s), by named, authorised, registered health professions, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for prescription or an instruction from a prescriber. They are written instructions for the supply or administration of medicines to groups of patients who may or may not be individually identified before presentation for treatment. They are NOT a form of prescribing[24].

PGDs cannot be used by podiatrists to supply or administer the controlled drugs their patients need from schedules 2 and 3. This means that PGDs cannot include tramadol hydrochloride, pregabalin or gabapentin (which are listed in schedule 3). For more information about the scheduling of controlled drugs, see appendix A.

4.2.1.3 Exemptions

The law defines some medicines as prescription only medicines, which normally need to be prescribed by a doctor or another prescriber before they can be administered or supplied to a patient. However, there are a range of exemptions from these restrictions which allow certain groups of health professionals – for example, midwives, podiatrists, optometrists, paramedics and orthoptists – to supply and administer listed prescription only medicines direct to patients.

[23] Specialist Pharmacy Service (2018) Questions about patient specific directions
[24] NICE (2017) *Patient group directions: medicines practice guideline*

Since 1980, podiatrists have had the legal ability to supply and administer medicines from a list of exemptions in medicines legislation. The list of exemptions in medicines legislation was extended in 2011 to include dihydrocodeine and some commercially available pre-mixed medicines, such as lidocaine and methylprednisolone combinations. The resultant list includes selected local anaesthetics, antifungals, analgesics, anti-inflammatories and antibiotics.

The proposed controlled drugs are not included in the current exemptions list as they are only appropriate for use by advanced podiatrist practitioners who are also independent prescribers and not the whole podiatric workforce.

4.2.2 Prescribing mechanisms

4.2.2.1 Supplementary prescribing

Podiatrists have been able to train to become supplementary prescribers since 2005; there are currently 511 qualified podiatrists annotated as supplementary prescribers on the HCPC register[25]. Using supplementary prescribing, the podiatrist prescribes in partnership with a doctor and the patient within a written clinical management plan (CMP) which must be created before any prescribing can take place.

A CMP can include almost any licensed or unlicensed medicine, including all controlled drugs from schedules 2-5. Supplementary prescribing can work well in the management of long-term conditions where there is a clear existing diagnosis and the doctor is part of the patient pathway to enable a CMP to be created or reviewed. Patients who benefit from podiatrists using supplementary prescribing include those with lower limbs at increased risk of ulceration and/or amputation through disorders such as diabetes or peripheral arterial disease.

However, for services in which the team is fragmented across sites, where there is no medical input, or when patients require a medicine that is not included in the CMP, use of supplementary prescribing can be difficult and patients may need to see other prescribers to receive some or all the medicines they need.

4.2.2.2 Independent prescribing

Since 2013, an advanced podiatrist practitioner who has undergone additional HCPC-approved training can practise as an independent prescriber as well as a supplementary prescriber. All prescribing programmes approved for podiatrists by the HCPC offer preparatory education towards dual annotation as supplementary and independent prescribers. There are currently 511 podiatrist prescribers on the HCPC register, 441 of which are annotated as both independent and supplementary prescribers[26].

4.2.2.3 Independent prescribing of controlled drugs

Legislation enacted in 2015[27] enables podiatrist independent prescribers in England, Scotland and Wales to prescribe from a restricted list of four controlled drugs, namely:

[25] HCPC supplementary prescribing data – September 2020
[26] HCPC independent prescribing data – September 2020
[27] *The Misuse of Drugs (Amendment) (No. 2) (England, Wales and Scotland) Regulations 2015*

temazepam	(schedule 3)	- oral administration
lorazepam	(schedule 4 part 1)	- oral administration
diazepam	(schedule 4 part1)	- oral administration
dihydrocodeine tartrate	(schedule 5)	- oral administration

Since November 2019, legislative changes have permitted the prescribing of the same controlled drugs in Northern Ireland.

The current list of four controlled drugs continues to be useful for prescribing by podiatrist independent prescribers where it is clinically indicated for a named patient.

However, patients that are being treated by podiatrist independent prescribers and that require controlled drugs other than those listed above may need to be referred to other prescribers, to receive the additional medicines. Further benefit could be gained by extending the range of controlled drugs that podiatrist independent prescribers could prescribe which will help ensure patients receive the right treatment and at the right time, including appropriate pain management in line with evidence-based practice.

4.3 Rationale for the selection of the additional controlled drugs

4.3.1 Controlling of medicines

When a prescription only medicine is classified under the Misuse of Drugs Act 1971 and placed in one of the schedules of the Misuse of Drugs Regulations, it becomes known as a controlled drug. The impact of this change is that it prevents the medicine being prescribed by a podiatrist independent prescriber, even though best practice evidence for its use has not changed, because the medicine is not included in the restricted list of controlled drugs that they can prescribe. The UK-wide consultation on proposals to introduce podiatrist independent prescribing took place in 2011[28] but it was not until 2015 that legislation was enacted to enable podiatrist independent prescribers to prescribe controlled drugs in England, Scotland and Wales; and November 2019 in Northern Ireland.

Podiatrist independent prescribers are prevented from prescribing any medicines which have been scheduled as controlled drugs after the date of the consultation in 2011. An amendment to the Misuse of Drugs Regulations in 2014 to include tramadol hydrochloride as a schedule 3 controlled drug resulted in podiatrist independent prescribers being no longer able to prescribe tramadol hydrochloride for their patients. If tramadol hydrochloride had been classified prior to the public consultation in September 2011 then it would have been included in the proposed list of controlled drugs at that stage.

In 2017, the Home Office consulted on proposals to schedule pregabalin and gabapentin as controlled drugs under the Misuse of Drugs Regulations 2001[29]. This followed the recommendation to ministers by the Advisory Council on the Misuse of Drugs (ACMD) that these two medicines should be placed in Schedule 3 of the Misuse of Drugs Regulations alongside their classification as Class C medicines under the Misuse of Drugs Act 1971.

[28] Department of Health (2011)) *Consultation On Proposals To Introduce Independent Prescribing By Podiatrists*
[29] Home Office (2017) *Pregabalin and gabapentin: proposal to schedule under the Misuse of Drugs Regulations 2001*

Following the consultation response[30] published in October 2018, both pregabalin and gabapentin were listed in schedule 3 of the Misuse of Drugs Regulations without the application of safe custody requirements from April 2019. It is therefore being proposed that gabapentin and pregabalin are added to the proposed list of controlled drugs that podiatrists can independently prescribe so that they can continue to prescribe these medicines for their patients.

4.3.2 Management of pain for effective treatment

As part of the ongoing care of their patients, podiatrist independent prescribers are expected to manage pain which may be as a result of the condition they are treating, during the podiatric treatment or during recovery following the treatment.

Assessment of pain, including regular, frequent review is fundamental prior to and during the prescribing of analgesia. The World Health Organisation (WHO) analgesic pain ladder[31] provides a guide to relevant medicines in the management of non-cancer pain where an assessment of pain has been undertaken and is accepted good practice in making analgesia-choice decisions. Since its initial creation for cancer pain, its use has been broadened to include the management of acute and chronic non-malignant pain in adults[32]. The analgesic ladder provides a three-step approach of sequential use of medicines according to the pain level reported by the patient. The figure below gives a visual illustration of the analgesic ladder.

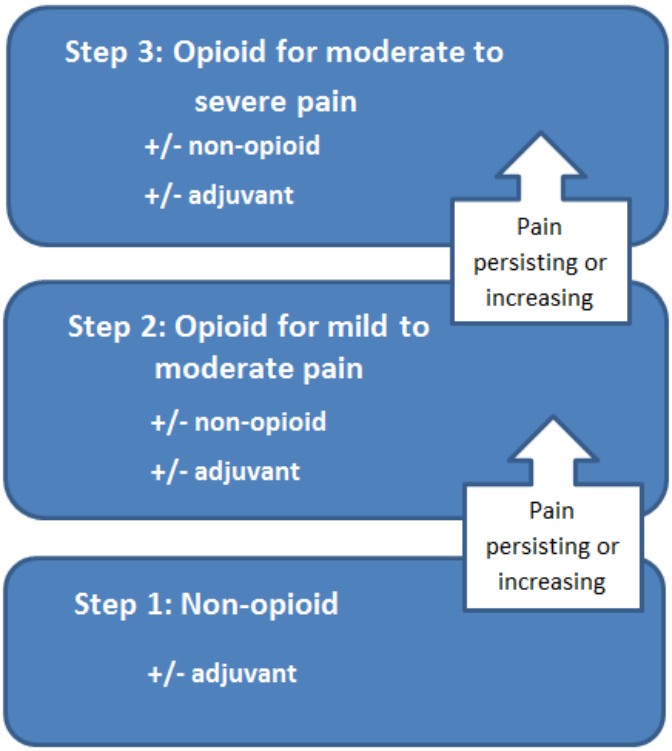

Figure 1: World Health Organisation (WHO) analgesic ladder (adapted)[33]

[30] Home Office (2018) *A consultation on proposals to schedule pregabalin and gabapentin under the Misuse of Drugs Regulations 2001: Government response to the consultation*

[31] World Health Organisation (1996) *Cancer pain relief with a guide to opioid availability*

[32] World Health Organisation *Impact of impaired access to controlled medications.*

[33] Welsh Medicines Resource Centre (WeMeReC) (2014) *Management of chronic non-malignant pain*

At the current time, podiatrist independent prescribers can prescribe almost all licensed medicines that step 1 relates to, and only some of the analgesics on steps 2 and 3 of the analgesic ladder, but not a wide range. This means that where a patient finds one choice of medicine unsuitable for their needs, the podiatrist independent prescriber may be unable to prescribe an appropriate alternative from the same class or step, even when clinical guidelines indicates that an alternative should be used. Subject to local formulary or guideline variation, tramadol hydrochloride can be used as a second choice for pain, needing a step 2 treatment if codeine phosphate is not tolerated or is ineffective. Likewise, morphine sulfate can be useful as a first choice for pain, needing a step 3 treatment if step 2 treatments are ineffective. Currently, the patient may face additional delays to their treatment whilst waiting for a medical prescriber to modify their medicines regimen.

Management of pain may include stopping medicines because they are no longer needed or no longer effective and need to be changed to another medicine. In order to cease the prescribing of any medicine (de-prescribing) the podiatrist independent prescriber must be able to prescribe that medicine, therefore if a podiatrist independent prescriber identifies that a patient is being prescribed tramadol hydrochloride unnecessarily they are unable to stop the prescription themselves but must refer the patient to another prescriber.

There are also a number of national guidelines which recommend the use of the four proposed controlled drugs for the treatment of pain in conditions that are commonly treated by podiatrist independent prescribers[34] [35] [36] [37] [38]. It is therefore desirable that podiatrist independent prescribers are able to prescribe these medicines to mitigate the need for their patients to see another prescriber, usually a GP, just to access the medicines of choice as recommended within national guidelines.

4.4 Benefits of the proposal

Under the proposals, patients in contact with podiatrist independent prescribers who can prescribe a wider range of controlled drugs would be able to receive the care and medicines they need, without having to see another prescriber. A greater number of patients could benefit from improved care, first time and in the right place. Effective utilisation of the workforce is also essential in meeting the triple aim of the *Five Year Forward View* by enabling improvements in health and wellbeing, reducing duplication and fragmentation of care and making best use of the resources available in addition to improving patient outcomes and their experience of care[39].

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

If the proposal is adopted, timely access to appropriate pain relief in conjunction with podiatric intervention would be possible, without the need for additional appointments with other health professionals to access medicines required. This would mean that patients will need to make fewer repeat GP / hospital attendances and the full treatment plan could be undertaken in one series of appointments with the podiatrist independent prescriber. Stopping the prescription of medicines is also a prescribing responsibility; early de-

[34] NICE (2014) *Clinical guideline (CG177) osteoarthritis: care and management*
[35] NICE (2015) *Clinical Knowledge Summaries: mild to moderate pain*
[36] NICE (2015) *Clinical Knowledge Summaries: peripheral arterial disease*
[37] NICE (2017) *Clinical guidelines (CG173) Neuropathic pain in adults: pharmacological management in non-specialist settings*
[38] NICE (2015) *Clinical knowledge summaries: restless legs syndrome: prescribing: pregabalin*
[39] NHS England (2014) *Five year forward view*

prescribing of controlled drugs when indicated lessens the risk of both tolerance and dependence.

4.4.2 Reduced delays

Many podiatric interventions in both primary and acute settings are podiatrist-led and therefore access to a doctor is not always possible. Podiatrist independent prescribers can make prescribing decisions and prescribe the required medicines during their consultation with a patient. If the proposals are adopted, there may be fewer delays for patients whilst waiting for a doctor to review a patient and consider prescribing controlled drugs. This could allow quicker management of acute symptoms, reducing absenteeism by workers who need to take time off work to attend appointments, enable the swifter return to work for patients whose symptoms can be effectively controlled more quickly, and reduce the need for patients with greater functional disabilities to make duplicate visits.

4.4.3 Clearer lines of clinical responsibility and accountability

If as is proposed, podiatrist independent prescribers were able to prescribe the necessary pain relief for patients during the consultation instead of handing off the responsibility for prescribing certain medicines to a medical prescriber, lines of accountability and responsibility would be further clarified. Additionally, if as proposed, the podiatrist independent prescriber could prescribe all the analgesia the patient needed during the episode of care, this could enable the identification of dependence or misuse more quickly.

4.4.4 Reduced resource usage and cost effectiveness

The proposed amendments to the list of controlled drugs would ensure that the skills of an advanced podiatrist practitioner are effectively and fully utilised in providing integrated podiatric care with adjuvant medicines management. These roles have a demonstrated ability to free up both GP and hospital consultant appointment capacity by reducing the demand on doctors to provide medication reviews linked to podiatric intervention.

4.4.5 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[40].

If as proposed, podiatrist independent prescribers could prescribe further controlled drugs, they could better enable patients to get the best use of their medicines in line with the principles of medicines optimisation. For example:

- The proposed medicines are used in evidence-based clinical pathways of care.
- Short courses could be prescribed as the effect would be reviewed at each appointment.
- Should the medicine no longer be required then podiatrist independent prescribers could de-prescribe the medicine therefore ensuring patients only take those medicines that are needed.
- Podiatrist independent prescribers will have full access to patients' medical records and will be able to ensure as far as possible, that any additional medicines they prescribe do not interact with any existing medicines that the patient is taking.

[40] Royal Pharmaceutical Society (2013) *Medicines Optimisation: Helping patients to make the most of medicines Good practice guidance for healthcare professionals in England*

4.5 Use in clinical practice

The scenarios below are illustrative examples to demonstrate how podiatrist independent prescribers might prescribe the four proposed controlled drugs within clinical practice and the benefits to be gained from this proposal.

Scenario 1- tramadol hydrochloride

Tramadol hydrochloride is an opioid painkiller used to treat moderate acute pain. It may be used when simple painkillers are not appropriate and when other weak opioids, such as codeine phosphate, have not been effective. Patients who have operations involving the foot and ankle can benefit from the pain-relieving effects of tramadol hydrochloride to help them complete the early stages of their rehabilitation.

Some patients who have acute injuries and/or disease affecting the bones, joints, muscles, soft tissues and nerves (musculoskeletal conditions) may also benefit from its short-term use for its pain-relieving effects where codeine phosphate has not been effective.

Some podiatrists undertake surgical procedures of the foot and ankle in hospital settings and manage patient's post-surgical needs. They also work in podiatry departments and as part of multi-disciplinary teams providing care to patients with a myriad of foot, ankle and lower limb complaints. Good pain relief is essential to support effective recovery and give optimal benefits from podiatry care.

Podiatrists cannot currently independently prescribe tramadol hydrochloride. This means that if a patient receiving podiatry care requires tramadol hydrochloride to give effective pain relief the podiatrist must send the patient to see a doctor. This can mean that patients may temporarily deviate from their management if they feel it is too painful, which can slow their progress down and delay their overall recovery.

If podiatrists were able to independently prescribe tramadol hydrochloride, patients would be able to receive timely access to the appropriate pain relief they required to support their treatment and rehabilitation. This would include stepping down the patient's treatment to an alternative painkiller as the post-operative pain settles. Patients would experience fewer delays in their progress and would need to make fewer visits to a range of professionals to obtain effective short-term pain relief.

Scenario 2- morphine sulfate

Morphine sulfate is an opioid painkiller used to treat moderate to severe acute and chronic pain. It is considered when non-opioid painkillers are not appropriate and when other opioid medicines have not been effective. Patients who have operations involving the foot and ankle can benefit from the pain-relieving effects of morphine sulfate to help them complete the early stages of their rehabilitation. Some patients who have acute injuries and/or disease affecting the bones, joints, muscles, soft tissues and nerves (musculoskeletal conditions) may also benefit from its short-term use for its pain-relieving effects where other opioids has not been effective. Good pain relief is essential to support effective recovery and give optimal benefits from podiatry care.

Podiatrists cannot currently independently prescribe morphine sulfate. This means that if a patient under the care of a podiatrist would benefit from morphine sulfate to support their recovery, the podiatrist must send the patient to see a doctor, or they must wait until a doctor is available to discuss the case with the podiatrist. This situation currently occurs frequently and leads to delays in providing effective pain relief and rehabilitation.

If podiatrists were able to independently prescribe morphine sulfate, patients would be able to receive timely access to the appropriate pain relief they require to support their treatment and rehabilitation. Podiatrists would be able to provide optimum levels of care in line with good practice guidance. GP capacity could be improved through fewer interruptions for medication review.

Scenario 3- gabapentin

Unlike pregabalin, gabapentin may be commonly used for treating peripheral nervous system pain only (pregabalin can be used for both peripheral and central nervous system pain) from damage or irritation to the nerve roots in the neck or back which causes pain which is felt in the limbs (radiculopathy). When treating peripheral nervous system pain and either medicine could be used, some organisations prefer gabapentin to be used first line unless patients experience intolerable side effects. It must be carefully prescribed and monitored with the dose gradually increased and then decreased to ensure safe usage.

Patients who have acute or chronic nerve pain caused by long term conditions such as diabetes or vascular disease, along with those who have peripheral nerve-related musculoskeletal pain in their lower limbs may benefit from the use of gabapentin. Many patients will not need surgery and their condition can be managed effectively with the right medication alongside other adjuvant therapies. Some patients, however, will need surgery to remove the cause of the nerve irritation.

Until very recently, gabapentin has been independently prescribed by podiatrists as a prescription-only medicine. Since it was scheduled as a controlled drug on 1 April 2019, podiatrists can no longer independently prescribe it for their current or future patients. This means that if a patient requires a new prescription of gabapentin to manage their condition or requires alterations to their existing prescription to manage their reduction in its use, the podiatrist must send them to a doctor. This may lead to delays in providing effective pain relief, timely stepping down to an alternative lower dose or stopping the medicine (de-prescribing).

If podiatrists were able to continue to independently prescribe gabapentin, patients would continue to receive access to the appropriate pain relief they required to support their treatment and rehabilitation from musculoskeletal conditions affecting the nerves, without the delay of waiting for a GP appointment.

Scenario 4- pregabalin

Pregabalin may be used to treat pain from injury and/or damage to the nerves of the body which is known as neuropathic pain. This can be central nervous system pain (from the brain and spinal cord) or peripheral nervous system pain (the nerves in the limbs and body) often called radiculopathy. Pregabalin must be carefully prescribed and monitored with the dose gradually increased and then decreased to ensure safe usage.

Patients who have acute or chronic nerve pain caused by long term conditions such as diabetes or vascular disease, along with those who have peripheral or central nerve-related musculoskeletal pain in their lower limbs may benefit from the use of pregabalin. Many patients will not need surgery and their condition can be managed effectively with the right medication alongside other adjuvant therapies. Some patients, however, will need surgery to remove the cause of the nerve irritation.

Until very recently, pregabalin has been independently prescribed by podiatrists as a prescription-only medicine. Since it was scheduled as a controlled drug on 1 April 2019, podiatrists can no longer independently prescribe it for their current or future patients. This means that if a patient requires a new prescription of pregabalin to manage their condition or requires alterations to their existing prescription to manage their reduction in its use, the podiatrist must send them to a doctor. This may lead to delays in providing effective pain relief, timely stepping down to an alternative lower dose or stopping the medicine (de-prescribing).

If podiatrist independent prescribers were able to continue to prescribe pregabalin, patients would continue to receive the appropriate pain relief to support their treatment from neurological or musculoskeletal conditions without the delay of waiting for a GP appointment.

4.6 Management of potential risks associated with the proposal

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

There are a number of potential risks to the proposal to enable podiatrist independent prescribers to prescribe additional controlled drugs. The risks perceived are not unique to podiatrist independent prescribers; they are the same as those for other professions that prescribe controlled drugs such as nurses, pharmacists and physiotherapists. As such, they are mitigated against by the governance and safety processes detailed in section 5 that are already in place in organisations which employ prescribers that can prescribe controlled drugs. The main potential risks perceived of the proposal and a summary of the mitigating actions are included in table 1 below.

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

Potential risk	Potential solution
Increased demand for appointments with podiatrist independent prescribers	• Patients will already be seeing the podiatrist independent prescriber and receiving their medicines at additional appointments with other prescribers, therefore demand for appointments with podiatrist independent prescribers should be unchanged. • Whilst appointments with podiatrists may be slightly longer, the availability of other prescribers, usually doctors, could be increased.
Podiatrist independent prescribers may prescribe a controlled drug newly added to the list without having the required skills and knowledge about the medicine resulting in an increased risk of error	• Only advanced podiatrists who are qualified independent prescribers will be able to prescribe from the list of controlled drugs. • Podiatrist independent prescribers must only prescribe medicines within their scope of practice and competence and the HCPC has the powers to remove individuals from their register if the person falls below the standards required. • Podiatrist independent prescribers will be expected to include any additional controlled drugs in their personal formularies in order to demonstrate competence before prescribing them. • All prescriptions will be checked by a pharmacist during the dispensing process, in line with those from all prescribers.

Legislation change may not occur or may be delayed in one of the home countries, the impact of which could be that podiatrists working in Scotland, Northern Ireland or Wales are unable to prescribe from the expanded list of controlled drugs resulting in an inconsistency of care for patients across the UK.	• There is representation on the programme board for this work from all the devolved nations in order to synchronise UK-wide legislative change. • The professional bodies involved represent members across the UK and are working with colleagues within the home nations to raise awareness of the changes and the associated benefits.
NHS organisations may decide not to include the additional controlled drugs in their local formulary or guideline therefore patients seeing podiatrist independent prescribers employed by the organisation will not benefit from the change to legislation.	• The proposed medicines form part of current clinical care which is based on best evidence and clinical guidelines and therefore it is unlikely that organisations will not include the medicines in their local formulary or guideline. • As part of implementation, NHS England and NHS Improvement, the devolved administrations and the professional bodies will raise awareness of the changes to legislation and the benefits to be gained in order to promote consistency.
A podiatrist independent prescriber may prescribe the additional controlled drugs when the patient has already an adequate supply from another prescriber.	• The practice guidance for podiatrist independent prescribers published by the professional bodies advises about adequate communication with other prescribers, duration of supply of controlled drugs and for patients to be seen by as few prescribers as possible.
Where podiatrist independent prescribers are employed by and accountable to one NHS organisation while managing patients presenting in another, this could result in a lack of adequate communication and access to prescribing data, with a risk to patients of duplication or incomplete care.	• In line with national guidance, monitoring of controlled drugs prescribing activity should already be in place in organisations. • The practice guidance includes engagement with monitoring and audit activities, including liaison with the Controlled Drugs Accountable Officer. • Podiatrist independent prescribers will work within competence and personal formularies which need to demonstrate competence in relation to the prescribing of any controlled drugs.

5 Governance and patient safety

The following governance and patient safety measures are already in place in organisations which employ prescribers that prescribe controlled drugs. Some of the measures are statutory and some mandated by organisations. Podiatrist independent prescribers who are currently prescribing controlled drugs must be already compliant with the measures in place and the policies of the employing organisation, as well as the relevant HCPC standards.

5.1 Education that all non-medical prescribers receive on controlled drugs

The HCPC *Standards for Prescribing*[41] against which prescribing programmes are approved, includes the need for an understanding of the legal context relevant to the prescribing of controlled drugs. The *Competency Framework for all Prescribers*[42] describes the knowledge, skills and behaviours which a podiatrist independent prescriber needs to have, to be able to demonstrate that understanding by the end of the programme. The *Outline Curriculum Framework*[43] is derived from the competency framework and includes learning outcomes related to each of the competencies. Providers of prescribing education programmes must ensure that podiatrist prescribers must be able demonstrate the proficiencies outlined within the HCPC *Standards for Prescribing* at qualification and to maintain their annotation. As part of the process, education providers may follow the *Outline Curriculum Framework*. The competencies are grouped under a number of headings, such as public health, knowledge of medicines, record keeping etc. so that each aspect of prescribing of controlled drugs is considered fully. The aspect may be included under several themes to ensure the different knowledge and skills needed in each case are developed adequately.

Podiatrist independent prescribers who are currently prescribing pregabalin and gabapentin would likely not need any additional training to continue prescribing these. They should be able to appropriately apply their training in controlled drugs and any guidance updates to their existing prescribing practice.

Those competent in prescribing tramadol hydrochloride using supplementary prescribing may not need additional training but should ensure they are up-to-date.

Those who have not previously prescribed any of the four proposed controlled drugs must have the relevant skills, knowledge and experience relevant to prescribing that drug before doing so. As set out above, if they have not been suitably equipped to do this through their prescribing training, they should develop the relevant skills, knowledge and experience through CPD activities.

5.1.1 Dependence and misuse

Like all other non-medical prescribers, podiatrist independent prescribers are educated about the dependence and misuse potential of controlled drugs as part of HCPC approved

[41] Health and Care Professions Council (2013) *Standards for prescribing*
[42] Royal Pharmaceutical Society (2016) *A competency framework for all prescribers*
[43] Allied Health Professions Federation (2018) *Outline curriculum framework for education programmes to prepare: physiotherapists, podiatrists, therapeutic radiographers and paramedics as independent/supplementary prescribers and to prepare: diagnostic radiographers and dietitians as supplementary prescribers*

prescribing education programmes and must access further education as part of on-going CPD. For example, the *Outline Curriculum Framework* states in competence 4.7 'appreciates the potential for misuse of medicines' and competence 4.5 expects that learners will 'understand the national frameworks for medicines use' such as *NG46-Controlled Drugs: Safe use and Management*[44] which includes guidance for all prescribers.

Podiatrist independent prescribers receive training on the misuse of medicines from a public health, legal and ethical and scope of practice aspect. They would be required to assess, diagnose and prescribe as part of a multi-disciplinary team and if unsure about any part of the prescribing decision must be able to consult with colleagues including medical colleagues before prescribing, or decide not to prescribe and refer the patient to a senior medical colleague. For example, one of the learning outcomes listed in the *Outline Curriculum Framework* expects that a non-medical prescriber 'understands when to prescribe, not to prescribe, referral for treatment including non- pharmaceutical treatment and discontinuation of medicines.' The assessment may highlight other concerns such as mental health problems that may impact on the use of controlled drugs and precipitate an onwards referral.

During non-medical prescribing programmes, training in prescribing controlled drugs includes prescribing during known dependence; in addition, the consideration of reports affecting legislation and national guidance such as the Airedale Inquiry and the fourth report on the Shipman Inquiry on controlled drugs which have influenced the mandatory introduction into organisations of standard operating procedures related to all aspects of the handling and prescribing of controlled drugs.

5.1.2 Adverse drug reactions (ADRs), interactions and errors

Eighty percent of patients taking opioids will experience at least one adverse effect; patients should be advised about this before starting to take the medicine[45]. Podiatrist independent prescribers are educated on the recognition of ADRs and interactions between medicines including controlled drugs. The HCPC *Standards for Prescribing* requires that learners 'be able to identify adverse medicine reactions, interactions with other medicines and diseases and take appropriate action' (standard 1.10). In addition, the *Outline Curriculum Framework* covers the management of the symptoms experienced by patients in the event of an ADR which may include anaphylaxis. Aspects of good prescribing practice to avoid ADRs and drug interactions is also included such as scrutiny of past medical history including previous medicines, allergy status, and consideration of polypharmacy. 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 Medicines and Healthcare products Regulatory Agency (MHRA) should be notified via the Yellow Card Scheme[46].

Podiatrist independent prescribers are taught to explain potential ADRs to patients, how to avoid or manage them and when to get advice, in order to reduce distress and optimise medicines therapy. The public health issues section of the *Outline Curriculum Framework* related to the prescribing of all medicines including controlled drugs expects that learners can recognise and report ADRs and appreciate and anticipate the potential for misuse of medicines including under- or overuse. It may still be necessary to prescribe an opioid but the recognition of risk factors for dependence or misuse should help to determine the degree of monitoring and support needed to prescribe opioids safely.

[44] NICE (2016) *NICE guideline NG46: controlled drugs: Safe use and management*
[45] Welsh Medicines Resource Centre (WeMeReC) (2014) *Management of chronic non-malignant pain*
[46] MHRA *Yellow Card Scheme*

Podiatrist independent prescribing students are also required to demonstrate an in depth knowledge of the medicines they intend to prescribe to the university at which they study prescribing, to the Designated Medical Practitioner who will be assessing them in clinical practice and to their employing organisation on an ongoing basis during their prescribing career through the completion of a personal formulary. For example, competence 4.2 in the *Outline Curriculum Framework* states '…understands the potential for adverse effects and how to avoid/minimise, recognise and manage them' and competence 4.1 states '…only prescribes a medicine with adequate, up-to-date awareness of its actions, indications, dose, contraindications, interactions, cautions, and side effects'.

As part of CPD and organisational governance arrangements, non-medical prescribers must undertake additional learning which may include e-learning. Some organisations insist on additional training, especially related to opioids, before the prescribing of controlled drugs e.g. MHRA opioid e-learning package[47]. This package includes considerations about ADRs including management of the symptoms, the abuse potential of controlled drugs and the detection of atypical symptoms which may be indicative of existing dependence. Completion of such additional learning should be recorded as part of the ongoing review of the personal formulary. See section 5.3 for more information about personal formularies

Podiatrist independent prescribers are expected to report prescribing errors through the organisation's incident reporting process which may be submitted by the organisation to the National Reporting and Learning System[48]. This enables national and organisational learning; the podiatrist independent prescriber should also reflect on the error using local clinical supervision, governance and/or medicines safety mechanisms.

5.2 Engagement with Controlled Drugs Accountable Officer (CDAO)

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 including monitoring all controlled drug prescribing within their area. The CDAO is usually the chief pharmacist or other senior person in the organisation; the roles and responsibilities and the requirement to appoint a CDAO are governed by legislation[49] [50] [51]. The responsibilities of the CDAO include:

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

The CDAO has access to reports on the prescribing activity related to controlled drugs of all prescribers in the relevant organisation, including podiatrist independent prescribers. Analysis of the reports, including reference to the personal formulary and scope of practice of the podiatrist independent prescriber, enables the CDAO to identify appropriate prescribing and outliers, and to take appropriate action as necessary. All prescribers,

[47] MHRA (2015) *Opioid learning module*
[48] NHS Improvement National Reporting and Learning System
[49] *The Controlled Drugs (Supervision of Management and Use) Regulations 2013*
[50] *The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 (No 3239) (W. 286)*
[51] *The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009*

regardless of setting, must know who the local CDAO is and comply with any local monitoring and/or inspection requests that the CDAO may make.

5.3 Personal formularies

The *Outline Curriculum Framework*[52] expects students to develop a personal formulary of the medicines they intend to prescribe in their current role during their training to become a prescriber. A personal formulary is much more than a replication of a BNF entry; it describes the condition they wish to treat and with which medicine, the place of that medicine in the treatment plan and applicability to individual patients, any pharmacovigilance information, linkage with national and local guidance including local formularies in preparation for their role as a prescriber in their employing organisation.

It is a governance requirement, and an inclusion to most organisational non-medical prescribing policies, that non-medical prescribers are expected to demonstrate to the employing organisation an adequate level of knowledge and competence in the therapeutic area of their potential prescribing practice prior to prescribing and annually thereafter. For this purpose, employing organisations expect the non-medical prescriber to continue to maintain the personal formulary document and produce it on request. Any controlled drugs that the professional intends to consider prescribing must be included on the personal formulary and be within the prescriber's scope of practice and competence. Reflection on the *Competency Framework for all Prescribers*[53], *Good Practice in Prescribing and Medicines Management for Podiatrists*[54] and the HCPC *Standards for Prescribing*[55] is used to inform the personal formulary.

The HCPC requires that registrants only practise in those fields in which they have appropriate skills, knowledge and experience. In addition, the *Good Practice in Prescribing and Medicines Management for Podiatrists* sets the scope of podiatry prescribing as defined by the professional bodies. This ensures that individual podiatrist independent prescribers can describe their prescribing activities within both the framework of podiatry practice, and their own chosen area of clinical practice. Their area of clinical practice must fit within the scope of the podiatry profession, and this ensures that podiatry independent prescribing supports the use of medicines as adjuvant to podiatry intervention, rather than prescribing in isolation.

5.4 Communication of decisions to prescribe controlled drugs

Podiatrist independent prescribers must communicate effectively, using the most appropriate media, with other practitioners involved in the care of the patient. Prescribing is not an activity that occurs in isolation. Prescribing information must be shared with other health professionals who need to know the information for the benefit of the patient and this will include the patient's GP. Prescribers are required to decide the best methods of sharing this information within organisation policy requirements as applicable. Where possible, they will have access to information about other health professionals' prescribing decisions

[52] Allied Health Professions Federation (2018) *Outline curriculum framework for education programmes to prepare: physiotherapists, podiatrists, therapeutic radiographers and paramedics as independent/supplementary prescribers and to prepare: diagnostic radiographers and dietitians as supplementary prescribers*

[53] Royal Pharmaceutical Society (2016) *A competency framework for all prescribers*

[54] The College of Podiatry (2018) *Good Practice in Prescribing and Medicines Management for Podiatrists*

[55] Health and Care Professions Council (2013) *Standards for prescribing*

where they impact upon their own decisions. This will include communication across NHS and private practice boundaries where it is necessary to ensure that clinicians have appropriate information to inform their prescribing practice.

In line with national guidance, ideally, only one prescriber should prescribe controlled drugs for the patient; they may undertake a trial period and review need on a regular basis, monthly as a minimum. This is to ensure adherence, identify ADRs, and early signs of misuse or dependence. However, podiatry prescribing activity cannot be undertaken in isolation. Podiatrist independent prescribers should inform anyone else who may be in a position to prescribe for that patient of their actions to avoid prescribing errors, duplicate prescribing and diversion. This is most likely to be the patient's GP but may also include other health professionals. If a patient refuses to consent to the sharing of such information the podiatrist independent prescriber must explain the risks of not doing so. If the patient continues to refuse to give consent, the podiatrist independent prescriber must consider which course of action, including not to prescribe, would be in the best interests of the patient. This must be documented in the patient's records and any correspondence to the GP. Onward referral to a pain specialist may be the best approach.

Podiatrist independent prescribers must know what medication the patient is currently taking including over-the-counter and herbal preparations before prescribing new medicines and must take steps to ensure they have access to the primary source of prescribing information, which is likely to be the GP record. Non-pharmacological solutions must be considered first line such as podiatry interventions; the use of opioids may shift the patient's sense of control towards an external agent, i.e. medication, for the relief of pain, leading to the neglect of other treatment goals such as increased function and a return to normal activities[56,57]. Podiatrist independent prescribers are ideally placed in the management of pain as their primary focus is the maximisation and restoration of physical function and have demonstrated their cautious approach to the prescribing of controlled drugs.

5.5 Prescribing controlled drugs in private practice

Podiatrist independent prescribers may work outside of NHS settings. For example, they work for private hospitals or practices that provide services to NHS patients or they may provide wholly private care that is not commissioned by the NHS. As regulated health professionals, podiatrist independent prescribers working in clinical practice are governed and regulated by the same standards as those working in the NHS, and the standard of care to be provided is the same. The *Competency Framework for all Prescribers*[58], the *Good Practice in Prescribing and Medicines Management for Podiatrists*[59] and the HCPC *Standards for Prescribing*[60] apply in full to podiatrist independent prescribers working and prescribing in private practice.

Employers outside of 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. As in NHS settings, the prescribing of controlled drugs in private practice is monitored by a CDAO. In order to prescribe in private practice, an approved controlled drugs prescription pad must be

[56] Welsh Medicines Resource Centre (WeMeReC) (2014) *Management of chronic non-malignant pain*
[57] Von Korff M (2017) *Opioids for chronic musculoskeletal pain: putting patient safety first*
[58] Royal Pharmaceutical Society (2016) *A competency framework for all prescribers*
[59] The College of Podiatry (2018) *Good Practice in Prescribing and Medicines Management for Podiatrists*
[60] Health and Care Professions Council (2013) *Standards for prescribing*

obtained for Schedule 2 and 3 controlled drugs, through registering with, and the approval of, the local CDAO.

In summary: podiatrist independent prescribers who are currently prescribing controlled drugs from the existing list of four controlled drugs must be already compliant with the measures in place in the employing organisation as described above. Should legislation be amended, podiatrist independent prescribers will be required to continue to be compliant with the same measures when prescribing the proposed additional four controlled drugs.

6 Equality and health inequality considerations

We have undertaken an *Equality and Health Inequalities Screening Tool* in accordance with NHS England requirements. A review of the screening tool by the specialist NHS England team indicated that a full Equality and Health Inequalities assessment is required alongside the consultation to collate responses.

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

6.1 Public sector equality duty

Public bodies within England, Scotland and Wales have legal obligation under the Equality Act 2010[61], and are required to have due regard to the aims of the Public Sector Equality Duty[62] (PSED) set out at section 149 of the Equality Act 2010, in exercising their functions, such as when making decisions.

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

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

The PSED covers the following protected characteristics:

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

As this is a UK-wide consultation, due regard has also been given to the requirements of section 75(1) of the Northern Ireland Act 1998[63] 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

[61] Equality Act 2010
[62] Public Sector Equality Duty 2011
[63] Northern Ireland Act 1998

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

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

6.2 Health inequality duties

Health inequalities have been defined as 'differences in health status or in the distribution of health determinants between different population groups' by the World Health Organisation. The National Health Service Act 2006 as amended by the Health and Social Care Act 2012[64] 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.

[64] 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, podiatrists, other 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. We may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it but we cannot guarantee that confidentiality can be maintained in all circumstances.

7.6 Next steps

The proposed changes to medicines legislation and the findings of the consultation will be presented to the Commission on Human Medicines who make recommendations to Ministers regarding changes to the Human Medicines Regulations. Subject to the agreement of Ministers, the Medicines and Healthcare products Regulatory Agency (MHRA) will make the necessary amendments. The Human Medicines Regulations are co-signed by the Secretary of State and the Minister of Health in Northern Ireland and apply UK-wide so changes to them will apply across the four countries.

As this proposal is 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.

8 Appendices

8.1 Appendix A: Scheduling of controlled drugs

Schedule	Examples of control attributes	Examples of controlled drugs
Schedule 1	• no therapeutic use and a Home Office licence is needed to produce, possess, administer or supply	e.g. LSD, raw opium
Schedule 2	• certain prescription requirements (such as dose in words and figures, manual signature) • prescription valid for 28 days • specific requirements for requisition in community settings • specific requirements for disposal of surplus or waste medicines • safe custody requirements such as standard of lockable cupboard and recording in register	Includes diamorphine, morphine, amphetamines, ketamine
Schedule 3	• certain prescription requirements (such as dose in words and figures, manual signature) • prescription valid for 28 days • specific requirements for requisition in community settings • specific requirements for disposal of surplus or waste medicines • some medicines have safe custody requirements such as standard of lockable cupboard and recording in register	Includes minor stimulants and other controlled drugs (such as buprenorphine, temazepam, midazolam)
Schedule 4	• no specific prescription or custody requirements, • prescription valid for 28 days • medicines listed in part I have specific requirements for disposal of surplus or waste medicines	Divided into two parts: part I contains most of the benzodiazepines (except temazepam and midazolam) and non-benzodiazepines and Sativex®. Part II contains most of the anabolic and androgenic steroids, an adrenoreceptor stimulant, growth hormones
Schedule 5	• no specific prescription or custody requirements • prescription valid for 6 months	Certain controlled drugs (such as codeine phosphate, pholcodine and morphine) that are exempt from full control when present in medicinal products of specifically low strengths.

The information above is taken from the British National Formulary[65]

[65] NICE (2018) *British National Formulary: controlled drugs and drug dependence*

8.2 Appendix B: Contributors

8.2.1 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 (from 14.1.19)
Lois Quayle (from 1.10.19)	NHS England and NHS Improvement	Programme Lead
Claire Potter	Department of Health and Social Care	Medicines Regulation & Prescribing
Graham Prestwich	NHS England and NHS Improvement	Patient & Public Representative
Bill Davidson	NHS England and NHS Improvement	Patient & Public Representative
Anne Ryan	Medicines and Healthcare products Regulatory Agency	Policy Division
Katherine Gough	NHS Dorset CCG	Head of Medicines Management
Dr Joanne Fillingham	NHS Improvement	Clinical Director Allied Health Professions, Deputy Chief AHP Officer
Professor Iain Beith	Council of Deans for Health	Head of a multidisciplinary Health and Social Care School
Graham Mockler	Professional Standards Authority	Head of Accreditation
Samina Malik	Health Education England	Senior Education and Training Policy Manager
Jan Beattie	Scottish Government	Allied Health Professions Officer for Primary Care
Dr Rob Orford	Welsh Government	Chief Scientific Adviser (Health)
Dr Mark Timoney (until 7.12.18)	Northern Ireland Government	Chief Pharmaceutical Officer
Hazel Winning (from 1.1.19 – 1.9.19)	Northern Ireland Government	Lead Allied Health Professions Officer
Steven Sims	NHS England and NHS Improvement	Programme Coordinator
Victoria Ryan (until 11.12.18)	NHS England and NHS Improvement	Programme Administrator

8.2.2 Lists project working group

Name	Organisation	Role
Dr Bruce Warner (Chair)	NHS England and NHS Improvement	Deputy Chief Pharmaceutical Officer
Shelagh Morris (until 30.6.18)	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 (from 14.1.19 – 30.9.19)
Lois Quayle (from 1.10.19)	NHS England and NHS Improvement	Programme Lead
Pip White	The Chartered Society of Physiotherapy	Professional Adviser
Dave Baker	The Chartered Society of Physiotherapy	MSK Practitioner and Independent Prescriber
Professor Alan Borthwick	College of Podiatry	Professional Adviser
James Coughtrey	College of Podiatry	Professional Adviser
Martin Harvey	Institute of Chiropodists and Podiatrists	Professional Adviser
Jill Burnett-Hurst	Institute of Chiropodists and Podiatrists	Professional Adviser
Andy Collen (until September 2018)	College of Paramedics	Professional Adviser
David Rovardi (from September 2018)	College of Paramedics	Professional Adviser
Richard Fitzgerald	NHS England and NHS Improvement	Patient & Public Representative
Rebecca Harmston	NHS England and NHS Improvement	Patient & Public Representative
Steven Sims	NHS England and NHS Improvement	Programme Coordinator
Victoria Ryan (until 11.12.18)	NHS England and NHS Improvement	Programme Administrator

8.3 Appendix C: Role of the professional bodies

The College of Podiatry
The College of Podiatry is part of the largest professional body representing chiropodists and podiatrists in the UK, collectively called The Society of Chiropodists and Podiatrists. Currently there are 9130 members, of which 212 are registered as active independent prescribers. The Society of Chiropodists and Podiatrists engages in most of the employment-related and membership support activity, and trade union representation, whilst the College of Podiatry has a remit that encompasses practice, education and research. The College works with key stakeholders internally within the profession and externally across the healthcare sector to support and develop the recognition of podiatrists as key members of the healthcare team, working in autonomous roles and as part of multidisciplinary teams in the NHS and independent practice.

The Institute of Chiropodists and Podiatrists
The Institute of Chiropodists and Podiatrists is the second largest professional body representing chiropodists and podiatrists in the UK. Originally founded as the Joint Council of Chiropodists of Great Britain and Ireland in 1938, and renamed the Institute of Chiropodists in 1955, they are a national membership organisation for HCPC registered chiropodists / podiatrists, providing professional support services, post-registration training, ethical guidance and indemnity insurance for members who are predominantly in private practice. The Institute's medicines and procedures advisory panel is drawn from experienced senior Institute members including podiatrist independent prescribers and consultant podiatrists who provide best-practice advice and guidance on matters of medicines use in podiatry for members, the public and the national media.

8.4 Appendix D: Entry criteria for prescribing education programmes

The entry criteria listed below are from the *Outline Curriculum Framework*[66] and are in response to the less prescriptive entry requirements of the HCPC *Standards for Prescribing*[67]. Only education programmes which employ entry criteria which meet the HCPC standards are eligible for HCPC approval.

a) Be registered with the HCPC in one of the relevant Allied Health Professions

AND

b) Be professionally practising in an environment where there is an identified need for the individual to regularly use independent prescribing or supplementary prescribing

AND

c) Be able to demonstrate support from their employer/sponsor* including confirmation that the entrant will have appropriate supervised practice in the clinical area in which they are expected to prescribe

AND

d) Be able to demonstrate medicines and clinical governance arrangements are in place to support safe and effective supplementary and/or independent prescribing

AND

e) Have an approved medical practitioner, normally recognised by the employer/commissioning organisation as having:

i) Experience in the relevant field of practice
ii) Training and experience in the supervision, support and assessment of trainees
iii) Has agreed to:
-provide the student with opportunities to develop competences in prescribing
-supervise, support and assess the student during their clinical placement.

AND

f) Have normally at least 3 years relevant post-qualification experience in the clinical area in which they will be prescribing.

AND

g) Be working at an advanced practitioner or equivalent level.

AND

h) Be able to demonstrate how they reflect on their own performance and take responsibility for their own Continuing Professional Development (CPD) including development of networks for support, reflection and learning.

AND

i) In England and Wales, provide evidence of a Disclosure and Barring Service (DBS) or in Northern Ireland, an Access NI check within the last three years or, in Scotland, be a current member of the Protection of Vulnerable Groups (PVG) scheme

*If self-employed, must be able to demonstrate an identified need for prescribing and that all appropriate governance arrangements are in place

[66] Allied Health Professions Federation (2018) *Outline curriculum framework for education programmes to prepare: physiotherapists, podiatrists, therapeutic radiographers and paramedics as independent/supplementary prescribers and to prepare: diagnostic radiographers and dietitians as supplementary prescribers*
[67] Health and Care Professions Council (2013) *Standards for prescribing*

8.5 Appendix E: Frequently asked questions.

1) What assurances are there that it is safe to allow podiatrists a greater range of controlled drug prescribing as proposed?

Patient safety is of paramount importance. Podiatrist independent prescribers who are currently prescribing controlled drugs from the existing list of four controlled drugs must be already compliant with the measures in place in the employing organisation as described in section 5. Should legislation be amended, podiatrist independent prescribers will be required to continue to be compliant with the same measures when prescribing the proposed additional four controlled drugs.

Furthermore, increasing access to controlled drugs has the potential to improve patient safety by reducing the number of health professionals that patients need to see to get the medicines that they need, improving the use of medicines and creating clear lines of professional responsibility.

2) Why update the limited list of controlled drugs that podiatrists can prescribe independently as proposed?

The current list was consulted upon in 2011 and is now out of date. This is because the ways that health care is provided has changed, and some medicines have been scheduled as controlled drugs since the last list was created. It was not necessary to include them last time but scheduling does not automatically trigger an update to the lists.

There are many potential benefits for patients, commissioners and providers of updating the lists as proposed. By ensuring that podiatrist independent prescribers can prescribe the medicines their patients need, there is potential to improve quality of care-enhancing patient safety, clinical effectiveness and patient experience. This could be achieved by reducing delays in care, improving compliance in taking medicines; improving patient experience through increasing access, convenience, choice and improving productivity (see section 4.4 on benefits for further information).

3) Would prescribing costs increase?

This is not anticipated. Patients may be already receiving the medicines they need but from other prescribers at additional appointments to the appointment with the podiatrist so the prescribing costs should be neutral.

4) Who can prescribe controlled drugs currently?

At present, nurse and pharmacist independent prescribers can prescribe any controlled drug from schedules 2-5 with a few restrictions. Podiatrist independent prescribers can prescribe from a restricted list of four controlled drugs, physiotherapist independent prescribers from a restricted list of seven controlled drugs. Supplementary prescribers (nurse, pharmacists, optometrists, radiographers, physiotherapists, podiatrists, paramedics and dietitians) can prescribe any controlled drug from schedules 2-5 when they are working within a written clinical management plan with a doctor.

5) Would podiatrists in private practice be able to prescribe the proposed additional controlled drugs?

Yes, podiatrists in private practice are already able to prescribe controlled drugs provided certain criteria are met. They must have successfully completed a HCPC approved prescribing programme, be annotated on the HCPC register as an independent prescriber, the requirement must be within the scope of practice and they must have the required skills, knowledge and experience before prescribing any medicine. They must also be able to

demonstrate they have appropriate governance arrangements in place for their role as an independent prescriber, including the prescribing of controlled drugs. Section 5.5 of this consultation guide gives further detail about the requirements.

6) Would podiatrist independent prescribers need additional training to prescribe the proposed additional controlled drugs?

Podiatrist independent prescribers must have the relevant skills, knowledge and experience before prescribing any medicine; if their education and training did not provide this for a particular medicine, they should secure this through appropriate post-qualification learning and experience – i.e. CPD. They have been able to prescribe pregabalin and gabapentin until recently, prior to the medicines being scheduled as controlled drugs. If podiatrist independent prescribers have been prescribing pregabalin and gabapentin they would likely not need any additional training to continue prescribing these. They should be able to appropriately apply their training in controlled drugs and any guidance updates to their existing prescribing practice.

It is a HCPC regulatory requirement that, to maintain their professional registration, podiatrist independent prescribers must keep their knowledge and skills up to date and relevant to their scope of practice through CPD[68]. It is also an organisational governance requirement that they would declare their competence by the inclusion of the additional controlled drugs they need to prescribe in their personal formulary.

7) Would podiatrists be able to prescribe the four proposed controlled drugs for children?

Podiatrist independent prescribers are already able to prescribe controlled drugs for children if this falls within their scope of practice and competence. Podiatrists who work with children already have experience in the prescribing from the current list of controlled drugs. Governance requirements will include the addition of the proposed controlled drugs they need to prescribe to the podiatrist independent prescriber's personal formulary. In addition, local and national policies and procedures would need to be followed which address medicine management issues in paediatrics in general and specifically about the prescribing of controlled drugs.

[68] HCPC (2016) *Standards of conduct, performance and ethics*

9 Glossary

Term	Explanation
Administration of medicines:	Process by which a medicine is introduced into, or applied onto, the patient's body.
Chief Professions Officers' Medicines Mechanisms (CPOMM) Programme:	An NHS England and NHS Improvement programme of work to extend the supply, administration or prescribing responsibilities to regulated health professions where there is an identified need and benefit to patients. The programme aims to make it easier for people to get the medicines they need when they need them, avoiding the need for people to see additional health professionals just to receive medicines.
Commission on Human Medicines:	Advises ministers on the safety, effectiveness and quality of medicinal products and on changes to medicines law.
Continuing professional development (CPD):	Activities which help health professionals continue to learn and develop throughout their career to keep their skills and knowledge up to date so they are able to practise safely and effectively.
Controlled drugs:	Controlled drugs are prescription only medicines that are controlled by the UK-wide Misuse of Drugs Act 1971 based on their benefit when used in medical treatment and their harm if misused, and placed in one of the schedules of the Misuse of Drugs regulations. 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, produced, supplied and prescribed. The Misuse of Drugs Regulations state five schedules that include all controlled drugs. Schedule 1 has the highest level of control, but drugs in this group are virtually never used as medicines. Schedule 5 has a much lower level of control. See appendix A for further information.
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[69] [70] [71].
Department of Health and Social Care (DHSC):	The central government department with responsibility for leading the nation's health and

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

Term	Explanation
	social care system to help people live more independent, healthier lives for longer.
Formulary:	A medicines formulary is a list of approved medicines. It is used alongside other resources to promote safe and appropriate prescribing of medicines for patients.
Health and Care Professions Council (HCPC):	The regulator of 16 different health and care professions including podiatrists. 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.
Licensed medicine:	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 for which it is intended.
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 Act 1971:	The main purpose of the UK-wide Misuse of Drugs Act as the primary legislation is to prevent the misuse of controlled drugs and achieves this by imposing a complete ban on the possession, supply, manufacture, import and export of controlled drugs except as allowed by regulations or by license from the Secretary of State.
Misuse of Drugs Regulations:	The Misuse of Drugs Regulations 2001 set out those exceptions to the Act in England, Scotland and Wales. As this is a UK-wide consultation, reference to the Misuse of Drugs Regulations 2001 should also be read as the Misuse of Drugs Regulations (Northern Ireland) 2002.
Non-medical prescribing:	Prescribing by specially trained healthcare professionals who are not doctors or dentists.

Term	Explanation
	They include nurses, pharmacists, physiotherapists, podiatrists and radiographers. They work within their clinical competence as either independent and/or supplementary prescribers.
Prescription Only medicine (POM):	A medicine that is generally subject to the requirement of a prescription written by an appropriate practitioner (prescriber) before it can be administered or supplied to a patient. There are several exemptions that allow POMs to be administered or supplied without a prescription, including PGDs and exemptions listed in legislation.
Unlicensed medicine:	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.