Publications approval reference: PAR145

## Patient and public summary of:

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

**October 2020**

This is a summary of the full consultation guide '*Consultation on proposed amendments to the list of controlled drugs that podiatrists can independently prescribe across the United Kingdom'.*

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

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

**Equality and Health Inequalities Statement**

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

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

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

# Contents

# 1 Introduction to the consultation

## 1.1 What are we consulting on?

In collaboration with the Scottish, Welsh and Northern Ireland governments, we are consulting on proposed changes to enable podiatrist independent prescribers to prescribe four more controlled drugs for their patients (as outlined below). This would be in addition to the four they can already prescribe. The four additional controlled drugs being proposed are:

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

See section 4.5 of the full consultation guide for further detail about the proposed medicines.

Controlled drugs are medicines that have additional controls associated with 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 D in full consultation guide for further information about the schedules.

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 in any setting in which podiatrists work including the NHS, independent and voluntary sectors.

## 1.2 Why are the proposed changes being considered?

Podiatrists have been able to supply and administer medicines for many years, through the use of:

- patient specific directions (PSDs) since 1968
- exemptions since 1980
- patient group directions (PGDs) since 2000

More recently, podiatrists working at an advanced level have also been able to prescribe medicines for their patients through the use of:

- supplementary prescribing since 2005

- independent prescribing since 2013
- prescribing independently from a restricted list of controlled drugs since 2015 in England, Scotland and Wales, and 2019 in Northern Ireland.

Section 4.2 of this guide contains more information about these mechanisms.

Although, current ways of prescribing, supplying and administering medicines have improved patient care there could be greater benefit to patients if podiatrist independent prescribers were able to prescribe an extended range of controlled drugs as proposed.

The proposed additions would help patients to get the medicines they need without additional appointments with other health professionals, such as GPs, just to get the medicines they need. If podiatrist independent prescribers could prescribe from a larger list of controlled drugs they would be able to provide patients with the right pain relief at the right time and in the right place.

Further information on the benefits of this proposal and potential risks, and measures in place to manage the risks is presented in section 4.4 and section 4.6 of the full consultation guide respectively.

## 1.3 Supporting documents

The following documents provide additional information about the proposal:

- The *Consultation Stage Impact Assessment*, which focuses on what impact the proposed policy change is likely to have and highlights the costs, benefits and risks of the proposed changes.
- The practice guidance entitled *Good Practice in Prescribing and Medicines Management for Podiatrists* describes how podiatrist prescribers should prescribe medicines safely for patients.
- The *Outline Curriculum Framework* which dictates the knowledge and skills that a podiatrist independent prescriber should have learned whilst on prescribing education programmes before being qualified to prescribe. This document is in line with the *Competency Framework for all Prescribers*[1].

## 1.4 What you will be asked about

The consultation questions ask:

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

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

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

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

## 2 Background

A scoping project was undertaken in 2015 by NHS England and looked at the need for some health professions to supply and administer medicines to their patients. The report of the project made a number of recommendations, including that the patients being treated by podiatrist independent prescribers could benefit if additions were made to the list of controlled drugs that they can prescribe.

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

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

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

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

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

## 3 The podiatry profession

All podiatrists must be registered with the Health and Care Professions Council (HCPC), the regulatory body which sets the standards that all podiatrists are expected to meet. Once registered, podiatrists must show that they are completing regular education and that they continue to practise both safely and effectively within their scope of practice, in order to maintain their registration. There are currently 13,026[2] podiatrists registered with the HCPC in the UK. Podiatrists diagnose and treat a wide range of conditions affecting the lower limb.

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

The current way to achieve registration with the HCPC as a podiatrist in the UK is by completing a university degree. Once registered, podiatrists can choose to develop their skills and experience in a particular speciality, as well as develop new skills at an advanced level. These experienced and additionally trained podiatrists are known as advanced podiatrist practitioners. Some advanced podiatrist practitioners also undertake training to be able to prescribe medicines.

Podiatrists work in a variety of places such as hospitals, GP practices or in independent practice. No matter where they work, they must always meet the same high standard as set by the HCPC. Likewise, their employers must use the same standard of systems and checks to ensure that patient safety is maintained.

The professional bodies representing podiatrists across the United Kingdom are the College of Podiatry and the Institute of Chiropodists and Podiatrists.

# 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 medicines within their scope of practice and competence, podiatrist independent prescribers can currently prescribe four controlled drugs for their patients. Consequently, they have to refer patients to other prescribers, usually GPs, to receive the controlled drugs that they are currently not permitted to prescribe, even though they may 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 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.

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

**Limitations**
Existing ways by which podiatrists can supply, administer or prescribe certain controlled drugs may not best support the needs of some patients. For example, those patients whose pain cannot be adequately controlled or who experience intolerable side effects to the

controlled drugs currently available for prescribing by podiatrist independent prescribers would have to continue to visit another health professional, usually a GP, to receive the medicines they require. This can result in unnecessary delays for patients, duplication of appointments and possibly prolonged pain. More detail on the impact of this option and the limitations of the current mechanisms available to podiatrists can be found in section 4.2 of this guide.

**Option 2: addition of four controlled drugs to the current list of controlled drugs that podiatrist independent prescribers can already prescribe.**

**Benefits**
Podiatrist independent prescribers mostly prescribe controlled drugs for pain relief for their patients. Adding four more controlled drugs to the current list of controlled drugs would benefit those patients for whom these medicines work most effectively. The reasons for the selection of the four controlled drugs can be found in section 4.3 of this guide.

**Limitations**
The addition of only 4 controlled drugs to the current list of controlled drugs that podiatrist independent prescribers can 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 would be permitted to prescribe. This would most likely be because they need controlled drugs for a medical condition that is outside of the current 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 perceived benefit associated with this option which relates to the removal of 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 they would 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 list of controlled drugs that podiatrist independent prescribers can currently prescribe

## 4.2 Limitations of the current use of medicines mechanisms by podiatrists

Podiatrists are currently able to use exemptions, patient specific directions (PSDs) and patient group directions (PGDs) to supply and administer medicines. Some advanced podiatrist practitioners can also prescribe medicines as independent and supplementary prescribers.

### 4.2.1 Supply and administration mechanisms

#### *4.2.1.1 Patient specific directions (PSDs)*

A PSD is a written instruction from a prescriber to administer or supply a medicine to a named patient who has been assessed by the prescriber. PSDs are very useful; they are written to treat a single patient and can be used for a wide range of medicines. However, there are some difficulties such as that they require direct input from an independent prescriber (usually a doctor) which can be a problem when a prescriber is not available.

#### *4.2.1.2 Patient group directions (PGDs)*

PGDs are written instructions for medicines to be supplied and/or administered by groups of health professionals to groups of patients. They contain information about which health professionals can supply or administer the medicine, which patients they can see, and when they should involve a doctor. They are NOT a form of prescribing[3]. PGDs cannot be used by podiatrists to supply or administer all of the four controlled drugs we are consulting on.

#### *4.2.1.3 Exemptions*

Exemptions allow certain medicines listed in legislation to be administered to patients by podiatrists without using a PSD or a PGD. The list of exemptions in medicines legislation that podiatrists can use includes dihydrocodeine tartrate, some 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.

### 4.2.2 Prescribing mechanisms

#### *4.2.2.1 Supplementary prescribing*

An advanced podiatrist practitioner who has successfully completed additional training can prescribe medicines using supplementary prescribing. The podiatrist prescribes in partnership with a doctor and the patient using a written clinical management plan (CMP). The CMP is written specifically for the patient and lists the medicines that the supplementary prescriber can prescribe for that patient. The CMP requires a three-way agreement between the patient, the doctor responsible for the patient's treatment and the supplementary prescriber. There are currently 511 qualified podiatrists annotated as supplementary prescribers on the HCPC register[4].

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

[4] HCPC supplementary prescribing data – September 2020

Supplementary prescribing can work well in the management of patients with long-term conditions such as diabetes, where there is a clear diagnosis and the doctor is part of the patient's care plan. However, where a doctor is not available, or patients require a medicine that is not included in the CMP, patients may not get the right medicines they need at the right time. This can impact on their podiatric treatment and outcomes.

#### *4.2.2.2 Independent prescribing*

An advanced podiatrist practitioner who has successfully completed additional training can independently prescribe medicines. This means that they can prescribe medicines for their patients in line with clinical guidelines and as long as this is within their knowledge and ability. There are currently 511 podiatrist prescribers on the HCPC register, 441 of which are annotated as both independent and supplementary prescribers[5].

#### *4.2.2.3 Independent prescribing of controlled drugs*

In England, Scotland and Wales, podiatrist independent prescribers can currently prescribe from a list of four controlled drugs:

- temazepam
- lorazepam
- diazepam
- dihydrocodeine tartrate

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

The current list of four controlled drugs is still useful for prescribing by podiatrist independent prescribers; however patients could benefit more if four additional controlled drugs were added to the list.

## 4.3 Rationale for the selection of the additional controlled drugs

### 4.3.1 Controlling of medicines

Since 2011 when work first commenced to allow podiatrist independent prescribers to be able to prescribe from a list of four controlled drugs, some prescription only medicines have been scheduled as controlled drugs. This means that podiatrist independent prescribers cannot prescribe these medicines for their patients.

Tramadol hydrochloride was scheduled in 2014 and from April 2019 pregabalin and gabapentin were also scheduled as controlled drugs[6]. Consequently, it is being proposed that all three of these medicines are added to the current list of controlled drugs so that patients can continue to benefit from having these medicines prescribed by their podiatrist, where appropriate.

More detailed information on these changes can be found in section 4.3 of the full consultation guide.

[5] HCPC independent prescribing data – September 2020

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

### 4.3.2 Management of pain for effective treatment

As part of the ongoing care of their patients, podiatrist independent prescribers are expected to help effectively manage their patients' pain.

Existing arrangements may not best support the needs of patients, particularly those for whom the controlled drugs currently available via these arrangements provide inadequate pain relief or produce side effects that patients cannot manage. Those patients who are unable to access the most appropriate controlled drug for management of their pain from the podiatrist independent prescriber have 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.

## 4.4 Benefits of the proposal

Should legislation be amended, patients being treated by podiatrist independent prescribers who can prescribe more controlled drugs would be able to receive the medicines they need without having to see another prescriber, such as a GP. This would mean that patients do not have to wait to receive the medicines they need. It would also free up the time of other NHS staff, such as GPs, so that they can treat patients who do need to be seen by a doctor.

More time would be saved through patients returning to the same prescriber that they are receiving their podiatry treatment from should they need further advice about their medicines.

Section 4.4 of the full consultation guide contains further information about the benefits of this proposal, and specific examples of how each of the four controlled drugs might be prescribed by podiatrist independent prescribers can be found in section 4.5 of the full consultation guide.

## 4.5 Management of potential risks associated with the proposal

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

There are a number of potential risks to the proposal to enable podiatrist independent prescribers to prescribe additional controlled drugs. The risks perceived are the same as those for other professions that prescribe controlled drugs. As such, they are managed by the governance and safety processes detailed in section 5 below that are already in place in organisations which employ prescribers that are able to prescribe controlled drugs.

The potential risks of the proposal are included in table 1, section 4.6 in full consultation guide.

# 5 Governance and patient safety

The following governance and patient safety measures are already in place in organisations that employ prescribers that prescribe controlled drugs. Some of the measures must be followed by law, and some by organisational policy. Podiatrist independent prescribers who are currently prescribing controlled drugs must already be 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 independent prescribers receive on controlled drugs

The HCPC *Standards for Prescribing*[7], the *Competency Framework for all Prescribers*[8], and the *Outline Curriculum Framework*[9] describe the knowledge and skills that a podiatrist independent prescriber must be able to show by the end of a prescribing education programme. This includes knowledge about controlled drugs and in particular how to identify and manage addiction, misuse, and adverse drug reactions.

## 5.2 Engagement with the controlled drugs accountable officer (CDAO)

What CDAOs must do, along with the organisations who appoint them, is stated in law[10] [11] [12]. The CDAO is usually the chief pharmacist or another senior person in the organisation and is accountable for everything that happens with controlled drugs- for example how they are ordered, stored, prescribed and administered to patients. CDAOs have the same responsibilities in all organisations where controlled drugs are kept or used, including organisations outside of the NHS.

The CDAO has a responsibility to ensure that the organisation has a controlled drugs policy and a set of procedures detailing how to look after controlled drugs properly. Regular checks are also required to make sure these are followed by everyone who works in the organisation. Podiatrist independent prescribers must comply with these policies and procedures in order to keep their patients safe.

## 5.3 Personal formularies

In line with good governance procedures, podiatrist independent prescribers are expected to have an up-to-date personal formulary; this is a detailed list of the medicines they intend to prescribe. The list may only contain medicines which the podiatrist is permitted by law to prescribe.

[7] Health and Care Professions Council (2013) *Standards for prescribing*
[8] Royal Pharmaceutical Society (2016) *A competency framework for all prescribers*
[9] 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*
[10] *The Controlled Drugs (Supervision of Management and Use) Regulations 2013*
[11] *The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 (No 3239) (W. 286)*
[12] *The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009*

A personal formulary describes the medical conditions that the prescriber will treat and with which medicine; this is so that the prescriber can show that they have sufficient knowledge of the medicines and the conditions that they are used to treat before prescribing them. This must include any controlled drugs that the podiatrist independent prescriber intends to prescribe.

### 5.4 Communication of decisions to prescribe controlled drugs

When controlled drugs are being prescribed, good communication is important for two main reasons: firstly, so that the podiatrist independent prescriber has enough information to make the correct decision about prescribing for the patient; and secondly, so that other prescribers know about what medicines the patient has already had prescribed for them.

Before prescribing medicines for their patients, podiatrist independent prescribers must have available as much information about the patient's medical condition(s) as possible including which medicines they are currently taking and have taken in the past to make a safe and effective prescribing decision. They must also share information about what they have prescribed and why, along with any other relevant information, with other prescribers involved in the patient's care including the patient's GP. This should include communication between NHS organisations and private practice where necessary.

Podiatrist independent prescribers can already prescribe four controlled drugs. Therefore, under the proposal, the communication relating to the prescribing of the additional controlled drugs would be no different to what they already do.

## 6 Equality and health inequality considerations

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

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

### 6.1 Public sector equality duty

Public bodies across England, Scotland and Wales have legal obligations under the Equality Act 2010[13], and are specifically required to consider the aims of the Public Sector Equality Duty[14], as set out at section 149 of the Equality Act 2010 when making decisions. This means that NHS England and NHS Improvement should understand the potential effect of the proposal on people with characteristics that have been given protection under

[13] Equality Act 2010
[14] Public Sector Equality Duty 2011

the Equality Act 2010, especially in relation to their health outcomes and the experiences of patients, communities and the workforce. This will help us to consider whether the policy or practice will be effective for all people.

As this consultation is UK-wide, appropriate consideration has also been given to the requirements of the Northern Ireland Act 1998[15].

### 6.2 Health inequality duties

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

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

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

## 7 Consultation format

### 7.1 Who can respond to this consultation?

Everyone is welcome to respond. We hope to hear from the public, patients, patient representative groups, carers, voluntary organisations, healthcare providers, commissioners, doctors, pharmacists, podiatrists, 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 survey
- asking for a paper copy of the consultation response form to be posted to you by contacting: england.cpomedicinesmech@nhs.net

  Please complete this form and return it to:

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

[15] Northern Ireland Act 1998

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

## 7.3 Alternative formats

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

## 7.4 Engagement events

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

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

## 7.5 How your responses will be used

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

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

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

## 7.6 Next steps

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

As this proposal is 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 Glossary

| Term | Explanation |
|---|---|
| Administration of medicines: | Process by which a medicine is introduced into, or applied onto, the patient's body. |
| Chief Professions Officers' Medicines Mechanisms (CPOMM) Programme: | An NHS England and NHS Improvement programme of work to extend the supply, administration or prescribing responsibilities to regulated health professions where there is an identified need and benefit to patients. The programme aims to make it easier for people to get the medicines they need when they need them, avoiding the need for people to see additional health professionals just to receive medicines. |
| Commission on Human Medicines: | Advises the government on the safety, effectiveness and quality of medicinal products, and on changes to medicines law. |
| Continuing professional development (CPD): | Activities which help health professionals continue to learn and develop throughout their career to keep their skills and knowledge up to date so they are able to practise safely and effectively. |
| Controlled drugs: | Controlled drugs are medicines that are classified in the UK-wide Misuse of Drugs Act 1971 based on their benefit when used in medical treatment and their harm if misused. Strict laws exist to prevent them to being misused, being obtained illegally or causing harm. |
| 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[16] [17] [18]. |
| Department of Health and Social Care (DHSC): | The central government department with responsibility for leading the nation's health and social care system to help people live more independent, healthier lives for longer. |
| Health and Care Professions Council (HCPC): | The regulator of 16 different health and care professions including podiatrists. It maintains a register of health and care professionals that are fit to practise in the UK and is responsible for setting the standards of education, proficiency, conduct, performance, character and health for these professionals. |
| Independent prescriber: | A practitioner responsible and accountable for the assessment of patients with undiagnosed and diagnosed conditions and for decisions about clinical management, including the prescribing of medicines. |
| Licensed 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 it is intended. |

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

| Term | Explanation |
|---|---|
| Medicines and Healthcare products Regulatory Agency (MHRA): | Responsible for regulating all medicines and medical devices in the UK by ensuring they work and are as safe as possible. They are also responsible for making changes to medicines legislation that have been agreed by government. The MHRA is a part of the DHSC. |
| Patient group direction (PGD): | A written instruction for medicines to be supplied and/or administered by groups of health professionals to groups of patients. They contain information about which health professionals can supply or administer the medicine, which patients they can see, and when they should involve a doctor. |
| Patient specific direction (PSD): | A prescriber's written instruction for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis. |
| Prescription only medicine: | Medicines that normally need to be prescribed by a doctor or another prescriber before they can be administered or supplied to a patient. There are several exemptions that allow POMs to be administered or supplied without a prescription, including PGDs and exemptions listed in legislation. |
| Supply of medicines: | The processes undertaken, in response to formal orders, to issue medicines directly to the patient to take away. Patients then administer the medicine to themselves or allow others to help them. |

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.