

Good Practice in Prescribing and Medicines Management for Podiatrists

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INTRODUCTION

This consultation document on Medicines Practice Guidance has been prepared by the College of Podiatry (CoP) along with input from colleagues from the Institute of Chiropodists and Podiatrists (IoCP). The advice herein is for all those with annotation on the Health and Care Professions Council (HCPC) Register as Supplementary or Independent prescribers, whether a member of the CoP or the IoCP, on the conduct that is expected of all podiatrist prescribers. There is a clear expectation that podiatrist prescribers from both professional bodies will adhere to this guidance and ensure that they are accountable for their actions. Whilst this document remains the property of the CoP, the IoCP fully expects its members to adhere to the guidance therein.

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Foreword

I am delighted to introduce this document, which provides a clear and authoritative framework for podiatrists who extend their professional practice by becoming prescribers. It sets out the standards for excellence which will guide practitioners and ensure patient safety.

The scope of clinical practice in podiatry has extended considerably recently to include many procedures such as surgery which were previously only undertaken by doctors. At the same time research and new technologies have provided evidence for more effective treatment of many foot conditions. These advances contribute significantly to the wellbeing of many people and are especially important as we seek to support an ageing population. Good foot care, the avoidance of complications of chronic conditions such as diabetes, and the maintenance of mobility are crucial for independence and the prevention of social isolation, thus promoting both physical and mental health.

The authority to prescribe, either as independent or supplementary prescribers, further extends the capacity of podiatrists to contribute to the health of the nation. As the arrangements for the delivery of care within and outside the National Health Service, become more diverse, podiatrist prescribers will be well placed to offer convenient and timely care to all their patients.

This document will be an invaluable source of guidance as the profession continues to extend its scope of practice. It gives me great pleasure to commend it to podiatrists, other clinical professions engaged in prescribing and to patients.

Dr. June Crown CBE

Introduction

This Medicines Practice Guidance booklet provides advice on the conduct that is expected of podiatrists who are independent and / or supplementary prescribers and who are therefore annotated accordingly on the register of the Health and Care Professions Council (HCPC). This document is 'guidance'. 'Guidance' is information which a podiatrist has a duty to consider and is expected to consider as part of their decision-making process¹. If a podiatrist prescriber deviates from the advice given in this document, the reason for this should be carefully recorded. If a complaint is made against you, the Health and Care Professions Council's Fitness to Practise Committee may take account of this document and those to which it refers. A podiatrist prescriber will be expected to justify any decision to act outside the terms of this guidance. This Guidance document should be read in conjunction with the Health and Care Professions Council Standards, including the Standards of conduct, performance and ethics, the Standards of proficiency for Chiropodists / Podiatrists and standards for supplementary and independent prescribing.

The advice in this document applies to all sectors of health and social care provision in the United Kingdom where prescribing activities occur, as permitted by the prescribing legislation in each of the Home Countries separately. The law relating to prescribing in the NHS may not be comparable across England, Scotland, Wales and Northern Ireland. It is up to the individual to satisfy themselves of the law in the UK country in which they work and that good governance procedures are in place in their workplace setting.

¹ [2009] EWHC 281 - Servier Laboratories Ltd v NICE and others.

At the current time, prescribing is not permitted by podiatrists outside of the UK. Therefore, a podiatrist permitted to independently prescribe in the UK cannot perform this activity outside of UK jurisdiction.

Each section of this guidance carries equal weight and the document is not ordered in any priority order.

Throughout this document the use of the word 'must' indicates a legal or regulatory requirement, and the use of the word 'should' indicate what should follow in all normal circumstances.

Key Legislation & Terminology

Medicines use in the UK is controlled by a very clear framework governed by the terms of the Human Medicines Regulations 2012. Podiatrists must be absolutely clear that they understand this framework and the distinctions between the five core frameworks for medicines use.

<u>Patient Specific Directions</u> (PSD): A Patient Specific Direction is a written instruction from an independent prescriber for a medicine to be supplied and/or administered to a named patient (see glossary). A PSD is a direct instruction and does not require an assessment of the patient by the healthcare professional instructed to supply and/or administer. A PSD is not a form of prescribing. An independent prescriber (a doctor, dentist or other independent prescriber) may instruct the podiatrist to supply and/or administer a named medicine to a named patient. The podiatrist must only supply and administer the medicine in accordance with the instructions that are written by the independent prescriber. It is not good practice for oral instructions to be acted upon except in emergencies. A written record of instructions given under a PSD must be maintained.

Patient Group Directions (PGD): Patient Group Directions enable specified registered healthcare professionals to supply and/or administer medicines directly to patients that fit the criteria laid out in the PGD. PGDs are not a form of prescribing. A doctor and a pharmacist, in conjunction with the non-medical prescriber will define in writing the named medicines that may be supplied and/or administered under the PGD. The PGD must be drawn up in a specific way and contain certain information in order to be legally valid. The podiatrist must supply and administer the medicine in accordance with the instructions that are written within the PGD. PGDs are not valid in all healthcare delivery settings. The application of PGDs in clinical practice varies between the Home Countries. Individual podiatrists identified by PGD are eligible to supply and/or administer specified medicines and must satisfy specific educational and other criteria laid down within the PGD. These criteria are approved by a senior doctor and pharmacist.

<u>Statutory Exemptions</u>: Profession specific exemptions (established via Statutory Instrument) allow certain listed medicines to be sold/supplied and/or administered to patients by podiatrists who have attained the required qualifications and are recognised by the Health and Care Professions Council as competent to do so (as indicated by specific annotations to the HCPC register). Exemptions are not a form of prescribing.

In addition to, but separate from, the supplementary and/or independent prescribing annotations, appropriately qualified podiatrists who are registered with the Health and Care Professions Council may possess the following annotations permitting certain sale/supply and administration rights to the medicines listed in the exemptions:

- Prescription Only Medicines Administration
- Prescription Only Medicines Sale/Supply

The 'Prescription Only Medicines - Administration' annotation permits podiatrists registered with the Health and Care Professions Council (HCPC) to access and administer a specific range of parenterally administered local anaesthetic and other prescription only medicines. These are listed under the Human Medicines Regulations 2012. Only those who have attained the certificate of competence in local anaesthesia recognised by the Health and Care Professions Council may be so annotated.

The 'Prescription Only Medicines - Sale/Supply' annotation permits podiatrists registered with the Health and Care Professions Council to sell and supply certain prescription only medicines. This list of medicines is identified in the Human Medicines Regulations 2012. Only those who have attained the certificate of competence in the use of these medicines, recognised by the Health and Care Professions Council, may be so annotated.

<u>Supplementary Prescribing</u>: Supplementary prescribing is a voluntary partnership between an independent prescriber and a supplementary prescriber, to implement a patient-specific clinical management plan, with the patient's agreement. It enables a podiatrist to prescribe medicines to individual, named patients those medicines that have been defined in writing within a clinical management plan as appropriate to the needs of the named patient. The terms of use and definition of 'clinical management plan' are defined in law.

Possession of this annotation permits podiatrists registered with the Health and Care Professions Council to prescribe medicines as podiatrist supplementary prescribers acting within the terms of a clinical management plan, as identified in the Human Medicines Regulations 2012

<u>Independent Prescribing</u>: Independent Prescribing enables a podiatrist to autonomously prescribe medicines to individual, named patients appropriate to the needs of the patient. Possession of this annotation permit podiatrists registered with the Health and Care Professions Council to prescribe medicines as podiatrist independent prescribers.

However, please note that this guidance does not cover:

- Supply and administration of medicines via a Patient Group Direction
- Sale supply or administration of medicines via exemption orders, as these are not forms of prescribing (sale/supply and administration of medicines on the exemption lists are addressed in the HCPC's Standards of Proficiency which relate to existing undergraduate pharmacology training requirements)
- Ethical advice on generic issues around the use and supply of drugs and medicines in podiatric practice, which is covered in the College of Podiatry Code of Conduct²

Throughout this document, where the phrase 'independent prescriber' is used, it will refer to a medical doctor or dentist. Use of the title 'podiatrist independent prescriber' will be used to refer to an independent prescribing podiatrist.

Categories of Medicines

There are three legal categories of medicines, identified according to their potency and risk of adverse side effects and the need for the supply to be professionally supervised ². For easy reference these definitions are also included in the glossary.

1. Prescription Only Medicines (POMs). These medicines may normally only be sold or supplied against the signed prescription of an 'appropriate practitioner' ie a doctor, dentist, nurse prescriber, optometrist prescriber, pharmacist prescriber, radiographer prescriber (supplementary only), physiotherapist prescriber or podiatrist prescriber.

² College of Podiatry: Code of Conduct (First Published 2001) Revised 2015 https://cop.org.uk/about-us/governance/ accessed 06/04/2018

- 2. Pharmacy Only Medicines (P) must be supplied or sold by a pharmacist or under the supervision of a pharmacist in registered pharmacy premises (unless specified otherwise in a statutory exemption).
- 3. General Sales List Medicines (GSL) can be supplied direct to the public in an unopened manufacturer's pack at any lockable business premises.

In addition, Controlled Drugs (CD) are prescription only medicines restricted under the Misuse of Drugs Act (1971), and the classes of persons who are authorised to supply such medicines are defined under the Misuse of Drugs Regulations (2001), which also identifies 5 schedules governing such activities as import, export, production, supply, possession, prescribing and record keeping³.

Ethical requirements

In line with the broader policy agenda concerned with equality, diversity and inclusion, the Equality Act (2010) public sector equality duty relating to all organisations in receipt of public funding extends to areas such as employment, the provision of services and education (as well as the accessibility of buildings, websites and transport). As a result, it is necessary to ensure that the requirements of the Equality Act (2010) are satisfactorily addressed in the provision of educational programmes in supplementary and independent prescribing.

The Act defines several protected characteristics (for eg. race, age, disability, gender). These may be used to inform relevant policies designed to prevent or deal with discrimination, harassment or victimisation of a person, or group of people, who identify with any of these protected characteristics, including institutional discrimination and failure to provide fair access.

In particular, the general duty of the Act states that public authorities, in the exercise of their duties, must have due regard to the need to:

- Eliminate discrimination, harassment and victimisation;
- Advance equality of opportunity (removing or minimising disadvantage, meeting the needs of people who share a relevant protected characteristic or those who do not share it, and encouraging participation in public life or any activity in which participation is low);
- Foster good relations between people who share a protected characteristic and those who do not share it

Type of Podiatrist Prescribing

There are two types of prescribing which may be undertaken as a podiatrist prescriber: supplementary and independent prescribing. Some podiatrists will be qualified as both, others only as supplementary prescribers. The annotation on the register of the Health and Care Professions Council, will if a podiatrist is independent prescriber list them as such and/or a podiatrist supplementary prescriber. The mode of prescribing practice will depend upon the needs of the patient at the point of treatment. A supplementary prescriber can only prescribe in accordance with a clinical management plan.

The guidance in this document applies to both National Health Service (NHS) and private practice. It is up to the individual to ensure that arrangements for good governance are in place.

³Department of Health, Review of Prescribing, Supply and Administration of Medicines Final Report, London: DH,

Standards for Prescribing

The HCPC define the standards of proficiency that are required for prescribing by podiatrists. The standards include the proficiencies required to prescribe safely and effectively. These proficiencies are in addition to the proficiencies that apply to non-prescribing podiatry practice.

http://hcpc-uk.org/publications/standards/index.asp?id=692

The Scope of Podiatry Prescribing

Podiatrist prescribers should not be asked to prescribe for patients to make up for short-falls in other professional prescribing groups.

The purpose of podiatrist-prescribing is to support and enhance the delivery of podiatry to patients. As such, podiatrists will use prescribing to support and enhance the delivery of podiatry based therapeutic interventions that are aimed at addressing health and well-being needs of individuals and groups related to conditions of the foot ankle and associated structures.

Scope of Practice

The education and training programme in prescribing ensures podiatrists are equipped with the principles of prescribing, to enable them to be safe, effective and cost-effective prescribers. Podiatrist prescribers should ensure that they are able to apply the prescribing principles to their own area of practice, bearing in mind that this may be a requirement for continuing registration. Podiatrist prescribers must only prescribe within their scope of practice and understand that if they change clinical areas they will require a period of training before they are competent to prescribe in a new area.

An individual's scope of podiatry practice must fall within the overall scope of the profession, and thus an individual's podiatrist-prescribing practice must fall within the overall prescribing scope of the profession.

At the current time, prescribing is not permitted by podiatrists outside of the UK and therefore a podiatrist who would be permitted to independently and/or supplementary prescribe in the UK would not be permitted to perform this activity outside UK jurisdiction.

Prescribers must have sufficient education, training and competence to:

- Assess a patient's clinical condition
- Undertake a thorough history, including medical history and medication history (including over-the-counter medicines and complementary therapies)
- Diagnose where necessary
- Decide on management of the presenting condition and whether or not to prescribe and/or refer
- Identify appropriate products of medication as required
- Advise the patient on risks, benefit and outcomes of the medication
- Prescribe if the patient agrees
- Monitor the patient's condition, including any response to the medication prescribed
- Give lifestyle advice as appropriate
- Refer to other professionals if necessary

This Guidance underpins the principles of prescribing practice within the context of the full scope of podiatry practice. Single Competency Framework published by the National

Prescribing Centre provides further prescribing information grouped into the following domains:

- · Clinical and pharmaceutical knowledge
- Establishing options
- Communicating with patients
- Prescribing safely
- Prescribing professionally
- Improving prescribing practice
- Information in context
- The NHS in context
- The team and individual context

http://www.npc.co.uk/improving_safety/improving_quality/resources/single_comp_frame work.pdf

NICE published guidelines on best-practice in the care of all people who are using medicines and those who are receiving sub-optimal benefit from their medicines. Podiatrists should be familiar with the following guidance document and understand how and when to implement the recommendations within it:

NICE Guidance NG5: Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes http://www.nice.org.uk/quidance/ng5

Registration and Professional Liability Insurance (PLI)

Podiatrists who are member of the College of Podiatry (CoP) or the Institute of Chiropodists & Podiatrists (ICP) benefit from Professional Liability Insurance (PLI) as part of their membership. In order for their PLI to be in force (subject to the terms of the policy) members (podiatrists) must:

- Hold current registration with the HCPC
- Hold a current CoP/ICP membership in a category that provides PLI cover at the time that treatment or advice is given
- Be practising lawfully
- Be practising within the overall scope of the profession of podiatry

Prescribing is accepted within the overall scope of the podiatric profession and due to the requirement for a podiatrist to be practising lawfully for PLI to be in force, for prescribing to be covered as part of an individual's PLI the member must:

- Have an HCPC annotation showing his/her prescribing status as either an independent or supplementary prescriber
- Ensure that his/her continuing professional development is in line with his/her current or future practice, including prescribing

Whilst not an absolute requirement CoP/ICP members should inform their professional body of their prescribing status. Additionally they must not prescribe until they are satisfied that their HCPC entry has been updated.

Podiatrists who are not members of the CoP/ICP will need to ensure they have adequate insurance in place for their practice. They may be personally liable for any costs if they are not adequately or appropriately insured.

Many employers now expect individual health professionals to hold their own personal insurance in addition to any employer vicarious liability insurance that may be in force.

Section 1 - Guidance on Prescribing Practice

This section provides advice and guidance on prescribing practice. Having achieved the competencies for prescribing, podiatrists are expected to follow this advice in their practice.

The advice and guidance provided in this document applies to *all* settings in which a podiatrist may prescribe - within the NHS, private practice, prison service, armed forces or any other provision.

Practice Guidance 1: Licence to prescribe

- 1.1 You must only prescribe once you have successfully completed an approved programme and been annotated on the register of the Health and Care Professions Council as a recognised prescriber (which specifies either supplementary or independent prescribing).
- Podiatrists should comply with this and other guidance issued by the College of Podiatry, and with any statutory requirements applicable to their prescribing practice. Failure to do so may put their registration at risk.
- 1.3 The ability to prescribe is a privilege granted to you by legislation and your employer (if applicable) and should be seen in this light.

Practice Guidance 2: Accountability

- 2.1 As an Independent Prescriber you are professionally accountable for your prescribing decisions, including actions and omissions, and cannot delegate this accountability to any other person. As a supplementary prescriber you are wholly responsible for your prescribing decisions for the medicines listed within the CMP. The decision, however, to include medicines in a CMP may be shared between you and the registered medical prescriber.
- 2.2 You must only ever prescribe within your level of experience and competence, acting in accordance with the College of Podiatry Code of Conduct and Standards for Clinical Practice.
- 2.3 If you move to another area of practice you must consider the requirement of your new role and only ever prescribe within your level of experience and competence.
- 2.4 You must inform anyone who needs to know about any restrictions placed on your prescribing practice. In particular, other practitioners with dispensing responsibilities need to know about this. For example, your employer may operate a specific prescribing formulary and may not allow you to prescribe outside of this formulary. You must also inform the relevant authorities if you have any formal regulatory restrictions placed on your prescribing activity.
- 2.5 An example of a restriction that could be placed on your prescribing practice might be a local NHS policy that limited you to prescribing certain drugs. This restriction would only apply to your NHS practice for that employer and would not prevent you from prescribing these medicines in the context of private practice.

Practice Guidance 3: Assessment

- In order to prescribe for a patient, you must satisfy yourself that you have undertaken a full assessment of the patient, including a thorough history and, where possible, accessing a full clinical record.
- 3.2 You are accountable for your decision to prescribe and must prescribe only where you have relevant knowledge of the patient's health and medical history.
- 3.3 You must ensure a risk assessment has been undertaken in respect of the patient's current medication and any potential interaction with other medicines.
- 3.4 You must refer to an appropriate prescriber if you do not fully understand the implications of your prescribing practice in terms of the physiology or pharmaco-

- therapeutic action of medication prescribed *even though* you may be able to take a thorough and appropriate history, which leads to a diagnosis.
- 3.5 You should ensure you consider the effects of your patient's lifestyle which may affect the safety of the medicines you prescribe. This will include:
 - The effects of smoking, caffeine, alcohol
 - The effects of 'recreational' or 'street' drugs or those used to enhance physical or sporting performance
 - o The effects of over-the-counter medicines including herbal preparations
- 3.6 Where necessary you should request additional appropriate tests, relevant to the presenting condition and/or appropriate to the prescribing decisions to be made in order to assist your prescribing decisions. Appropriate biochemical and histopathological assessments should be undertaken where necessary and these may include:
 - Liver function tests
 - Thyroid function tests
 - Kidney function tests
 - Blood biochemistry tests

Practice Guidance 4: Need

- 4.1 You must only prescribe where you have assessed the patient and there is a genuine clinical need for treatment.
- 4.2 You must also consider the circumstances in which you may decide to withdraw medication, cease to continue prescribing a named medication or alter the prescribed dose of a medication. Patients may also wish to discuss with you withdrawal from medication at their choice. Any withdrawal from medicines needs to be planned in partnership with the patient and take place over an agreed time period
- 4.3 You should never prescribe for your own convenience or simply because a patient demands that you do.
- 4.4 You should prescribe in the patient's best interests and achieve this by reaching agreement with the patient on the use of any proposed medicine. The amount of information you discuss with your patient will vary according to the nature of the patient's condition, the risks and benefits of the medicine and the patient's wishes. In all circumstances this will include the provision of 'sufficient information' to allow the patient to make an informed choice i.e. to give their informed consent. You should aim to:
 - Establish the patients priorities, preferences and concerns
 - o Discuss other treatment options available to the patient
 - Satisfy yourself that you have enough relevant information to make a prescribing decision
 - Satisfy yourself that the patient understands how to take the medicine as prescribed
- 4.5 You must only prescribe for patients who are part of your own caseload or under your own care, you must not write up prescriptions for patients simply because you are the only prescriber around.

Practice Guidance 5: Consent

- 5.1 You must explain your role as a non-medical prescriber to the patient or their representative.
- 5.2 You must be aware of cultural and religious differences insofar as they apply to prescribing.

- As a podiatrist prescriber you must act in accordance with the College of Podiatry Code of Conduct (section 3), the Standards of Clinical Podiatric Practice in Primary Care (section 2) and the CoP Guidelines on Patient Consent. This must also be done in line with local Trust guidance from the PCT (for NHS employees).
- You must make it clear to the patient that prescribing activity cannot be undertaken in isolation. You should inform anyone else who may be in a position to prescribe for that patient of your actions in order to avoid prescribing errors. This is most likely to be the patient's general medical practitioner but may also include other medical or non-medical prescribers. If the patient refuses to consent to you sharing information you must explain the risks of not doing so. If the patient continues to refuse to give consent, you must consider which course of action would be in the best interests of the patient. This may include not prescribing in this case. This must be documented in their records.

Practice Guidance 6: Communication

- 6.1 You have a responsibility to communicate effectively with other practitioners involved in the care of the patient. You must refer the patient to another prescriber when it is necessary to do so.
- When prescribing, you must take the views of the patient into account in order to create an environment where shared-decision making is the norm. This will include considering the patient's personal views and beliefs and discussing treatments in relation to these.
- 6.3 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. You should decide the best methods of sharing this information. You should have access to other professionals' prescribing decisions. This will include communication across NHS-private practice boundaries where it is necessary to ensure that clinicians have appropriate information to inform their prescribing practice.
- 6.4 You must know what medication the patient is currently taking (including OTC and herbal preparations) before prescribing new medications and you must take steps to ensure you have access to the primary source of prescribing information which is likely to be the GP record.
- Documentation of your prescribing communications should be recorded as described in section 7 (Record keeping).

Practice Guidance 7: Record keeping

- 7.1 The College of Podiatry Code of Conduct, Standards of Clinical Podiatric Practice in Primary Care and the CoP Guidelines on Patients Records provide the underlying principles.
- 7.2 You should ensure records are accurate, comprehensive, contemporaneous and accessible by all members of a prescribing team (effective policies must be in place locally to enable this to happen).
- 7.3 In supplementary prescribing, the doctor/dentist and supplementary prescribers must share access to, consult and, wherever possible, use the same common patient record.

Practice Guidance 8: Evidence based Prescribing

8.1 Podiatrists should prescribe according to the available evidence base. Evidence-based prescribing involves the application of best available evidence when making prescription decisions. Reference to the evidence base can minimise the risk of adverse drug reactions and ensure effectiveness. An evidence-based approach is being devised as part of the development of 'The College of Podiatry Clinical Management Guidelines' for prescribers, which will become available online on the website of the College of Podiatry, under the section "Medicines". Wherever

- possible, evidence-based interventions will be recommended. Where the evidence base is minimal, recommendations are included where there is a clinical consensus for their effectiveness.
- The clinical management guidelines will be produced by the College of Podiatry, but it will be a freely available online resource to all supplementary and independent prescriber podiatrists when it is available.

Practice Guidance 9: Delegation

- 9.1 You may delegate the administration of a medicine that you have prescribed. You remain accountable for your prescribing decision and you are also accountable for your decision to delegate the task of administration to someone else. This includes your assessment that the person is competent to carry out the task and has received sufficient training to administer the prescribed medication. You are not accountable for the outcome of an action performed by another person.
- 9.2 You may not delegate administration of a medicine that you supply or administer via a Patient Group Direction (PGD) (see glossary for a definition of a Patient Group Direction). Medicines listed within a PGD can only be administered by the registered health professionals named on the PGD.
- 9.3 When delegating the administration of a medicine to someone else you should record in the appropriate record:
 - The name and profession of the person to whom you delegated the administration
 - o What you have asked them to administer
 - o How you have asked them to administer it
- 9.4 Where this information is not clearly identifiable from your written prescription then the information should be separately recorded in the patient record.
- You may delegate the administration of a medication to another competent person. You must only delegate administration if you are satisfied that the person is educated, trained and competent to administer the medicine safely.
- 9.6 You must provide direct supervision of any post-registration student podiatrist who is undergoing a period of training in the safe use of medicines.

Practice Guidance 10: Information given to patients

- 10.1 Patients, or those authorising treatment on behalf of the patient, should be given as much information as they require in order for them to make an informed choice with regard to prescribing decisions. You should include:
 - o Diagnosis giving rise to prescribing need
 - o Any known serious or common side effects of the proposed medicine
 - o How the medicine works
 - How long to take it for
 - o How to stop
- 10.2 Information provided must be appropriate to the patient's levels of understanding.
- 10.3 Where practicable you should support information given to your patients in writing.
- 10.4 You should tell the patient that their medicine will come supplied with a manufacturer Patient Information Leaflet which will give them additional information.

10.5 You must inform the patient if you propose to prescribe or use any medicine that is unlicensed or outside the terms of licence/marketing authorisation (including the use of 'mixed' medicines). This would include cases where there is little research or other evidence of current practice to support such use, or where the use of the medicine is innovative.

<u>Practice Guidance 11: Clinical Management Plans</u> (supplementary prescribing)

- 11.1 If you are prescribing as a supplementary prescriber, you must prescribe in accordance with a patient's individual clinical management plan (CMP).
- 11.2 The independent prescriber must have made the initial diagnosis of the patient
- 11.3 Where standard CMPs are in place as a starting point, you must tailor them to reflect the individual patient's personal, medical and medicines history. The CMP must be agreed with you by an independent prescriber and with the consent of the patient, before supplementary prescribing begins. This could be in the form of a signature, or for an electronic record and a recordable indication of agreement.
- 11.4 Within supplementary prescribing, you must refer the patient back to the independent prescriber should the patient's clinical circumstances change. It may then be decided that a CMP is no longer appropriate or may need amending to reflect the change in circumstances.
- 11.5 Within supplementary prescribing you must *never* prescribe medication in the absence of a written CMP which has been agreed with the independent prescriber and with the consent of the patient. The independent prescriber may agree verbally to a CMP providing that it is confirmed by fax or secure email before prescribing occurs, and formally recorded within two working days.
- 11.6 The prescribing of a Prescription Only Medicine (POM) by a supplementary prescriber outside a CMP constitutes a criminal offence under the terms of the Human Medicines Regulations 2012, and it is also possible that action would be taken by the Health and Care Professions Council under its Fitness to Practice procedures.
- 11.7 If a podiatrist who is both an independent and supplementary prescriber sees a patient as a supplementary prescriber they must adhere to the terms of the CMP when managing the patient's condition for which the CMP has been agreed. This does not preclude the podiatrist from prescribing medication for the patient for an unrelated condition, where the podiatrist is acting as an independent prescriber and is competent to treat the condition concerned. The patient should be told of the distinction between the authority to prescribe as an independent prescriber and that of a supplementary prescriber. They should be told that the podiatrist is acting as an independent prescriber in that instance.

Practice Guidance 12: Transcribing

This involves transferring medicines prescriptions from one document to another and in reality, is a request to re-prescribe existing medicines in a new setting. Transcribing should not be a routine or regular occurrence.

- 12.1 You are accountable for your decision to prescribe existing medicines for a patient in a new clinical setting.
- 12.2 You must satisfy yourself that a re-prescription of the medicine is clinically indicated and is in the patient's best interests.

Practice Guidance 13: Electronic Prescribing

Medicines and prescribing legislation underpin the safe and effective use of medicines. By adapting to advances in healthcare delivery, medicines legislation can enable clinicians to improve the patient experience through new roles, new ways of working, extended roles and service redesign, to enable flexible responsive and proactive services. One part of medicines management is 'e-prescribing'. Where it is used it will enable podiatrists to access better mechanisms of prescribing, supplying and administering medicines. For 'e-prescribing' to work effectively there is a clear indication that it be linked to a patient's electronic record. This allows for contraindications and interactions to be clearly identified. Although not currently accessible to many prescribers, it is expected that it will be implemented more widely.

- 13.1 You may prescribe via computer-generated prescriptions providing the necessary software is available to enable them to be signed with an advanced electronic prescription.
- 13.2 A visible audit trail of your prescribing actions must be maintained.
- 13.3 Prescriptions should always be signed immediately if not electronically approved.
- As an independent podiatrist prescriber, you should ensure you are appropriately trained to follow local protocol around 'E-prescribing'.

Practice Guidance 14: Writing NHS Prescriptions

- 14.1 Your written prescription must contain the information required by law:
 - o It must be signed in ink
 - o It must contain your name and workplace address
 - The date on which the prescription was signed by you and/or the date after which it can be dispensed
 - o Your profession
 - o The name and address of the patient
 - o The age of the patient if under 12 years old
- 14.2 The names of the medicines must be written clearly using approved names only. You must not use abbreviations in the name of the medicine.
- A non-repeat prescription is valid for six months after the date of signing, however you should ensure that the medicines prescribed are appropriate for the patient's needs as you have assessed them, so the reasons for any significant delay between assessment and prescription dispensing should be documented.
- 14.6 You must only write prescriptions for your NHS patients on an FP10 or In-patient Drug Chart. When using FP10's these must have been issued specifically to you for your NHS practice and show your name and HCPC registration number.
- 14.7 You must never tamper with an existing prescriber's details on a prescription form or add your own prescribing details.
- 14.8 You must sign your prescriptions immediately they are produced. If this is not possible (e.g. the prescription is printed in a dispensary away from your clinic room), the unsigned prescriptions must be securely stored until you can sign them. You must sign them within 24 hours.
- 14.9 You must never sign a blank prescription form in advance and then store them for future use.

<u>Practice Guidance 15: Writing Private Prescriptions</u>

- 15.1 Podiatrist independent prescribers may issue private prescriptions for any licensed medicine providing this falls within the recognised scope of practice and sphere of competence of the podiatrist. Supplementary prescribing may also operate in private practice, where any prescription must be in accordance with what has been agreed with the independent prescriber and the patient within the terms of the CMP.
- 15.2 The appropriate information as outlined in Practice Guidance 14 pertaining to process should be applied in this setting (in accordance with local protocols in private hospitals) too.

Practice Guidance 16: Reviewing Prescriptions

16.1 You should review a patient's medication regularly and in particular when you are staring a new medication, stopping a medication or changing a dose of a current medication.

Practice Guidance 17: Repeat Prescriptions

- 17.1 The plurality of provision within health services in both the NHS and in private practice will mean that repeat prescribing and the issue of repeatable prescriptions may become a significant aspect of the role of the podiatrist prescriber. The National Prescribing Centre in England has produced good practice guidelines: Saving time, helping patients: a good practice guide to quality repeat prescribing, available at www.npc.co.uk.
- 17.2 You may issue a repeat or repeatable prescription, but you should only do so in the knowledge that you are responsible as the signatory of the prescription and are accountable for your practice.
- 17.3 Before signing a repeat or repeatable prescription, you must be satisfied that it is safe and appropriate to do so and that secure procedures are in place to ensure that:
 - a) The patient is issued with the correct prescription.
 - Each prescription is regularly reviewed and is only re-issued to meet clinical need.
 - c) A case review takes place after six months.
 - d) Suitable provision is in place to ensure that patients who need a further examination or assessment do not receive a repeat prescription without first being seen by an appropriate prescriber.
 - e) A record is made of the repeat prescription on the patient's record.
- 17.4 Repeat prescriptions are valid for six months and, unless specified in writing on the prescription otherwise, the medicine may be dispensed twice within the validity of the prescription (with the exception of contraceptives, which may be dispensed six times). You should ensure that you review your patient's medication at regular intervals to ensure the prescription remains appropriate for your patient's needs.
- 17.5 If you issue repeat prescriptions, you must ensure that you prescribe safely and responsibly. Before signing repeat prescriptions, you must be satisfied that it is safe and appropriate to do so. You should review repeat prescriptions regularly and do not issue medicines for longer than is clinically required. If multiple medicines have been prescribed previously, ensure that all are needed on repeat. You should ensure the correct dose is prescribed for medicines where the dose varies according to the course of the treatment.

Section (2) - Special prescribing circumstances

Practice Guidance 18: Family, Friends & Colleagues

- 18.1 You must not prescribe medications to treat yourself. You should be registered with your own medical and/or health practitioner who will be objective in providing you with good care.
- 18.2 You should wherever possible avoid prescribing for those close to you. People close to you include your immediate family (for example parents, grandparents, children, grandchildren, siblings, aunts, uncles and first cousins), someone with whom you have an intimate personal relationship and your friends or colleagues.
- 18.3 You should avoid prescribing for family and friends unless:
 - No other prescriber is available to assess the patient's clinical condition and to delay prescribing would put the patient's life or health at risk, or cause intolerable pain
 - o The treatment is immediately necessary to:
 - Save life
 - Avoid serious deterioration in the patient's health and well-being
 - Alleviate otherwise uncontrollable pain
- 18.4 You must be able to justify your decisions to prescribe for family and friends. You must record the nature of your relationship and the special circumstances that necessitated your action of prescribing for family and friends.
- 18.5 At all time you must maintain an objective view of your patient's interests. See in particular Section 3, College of Podiatry Code of Conduct.

Practice Guidance 19: Prescribing for Children, Pregnancy & Older People

- 19.1 Medicines are potent treatments and prescribing them can present significant risk to patients. This is especially so for children and older people, whose responses may differ from adults (See Practice Guidance 21.4). It is essential that registrants recognise the unique implications for children and young people. Caution should also be taken when prescribing for pregnant and lactating women. Only podiatrists with relevant knowledge, competence, skills and experience in treating children should prescribe for children. Anyone prescribing for a child must be able to demonstrate competence to prescribe for children and to refer to another practitioner when working outside their area of expertise and level of competence.
- 19.2 In all cases reference should be made to the following documents that address medicines management issues in paediatrics:
 - The BNF for Children (England/Wales/Scotland) at www.bnfc.org
 - Medicines Standard: National Service Framework for Children, Young People and Maternity Services at www.dh.gov.uk under Policy and Guidance, Health and Social Care Topics, Children Services
 - Medicines Standard: National Service Framework for Children, Young People and Maternity Services (Wales)
 - Royal College of Paediatrics and Child Health information on use of licensed and unlicensed medicines at www.rcpch.ac.uk/publications
 - Scottish Executive The Administration of Medicines in Schools and The Right Medicine: A Strategy for Pharmaceutical Care in Scotland
 - SIGN Guidance at www.sign.ac.uk
 - DHSSPS Medicines Management Standard
 - DH Every Child Matters (2004)

Practice Guidance 20: Prescribing unlicensed medicines

- 20.1 You must not prescribe an unlicensed medicine as a podiatrist independent prescriber
- 20.2 You may prescribe an unlicensed medicine as a supplementary prescriber as part of a CMP providing:
 - The independent prescriber has agreed with you the clinical management plan with the patient's consent.
 - You are satisfied that there is a sufficient evidence base and/or experience to demonstrate the medication's safety and efficacy for that particular patient.
 - You and the independent prescriber are prepared to take the responsibility for prescribing the unlicensed medicine and have agreed the patient's CMP to that effect.
 - o The patient agrees to a prescription in the knowledge that the drug is unlicensed and understands the implications thereof.
 - The medication chosen and the reason for its selection is documented in the CMP.

<u>Practice Guidance 21: Prescribing medicines for use outside the terms of the licence/marketing authorisation ("off-label" use)</u>

- 21.1 Off-label prescribing is where a licensed medicine is prescribed outside the terms of its product licence. There may be circumstances where podiatrists may prescribe licensed medicines for use outside the terms of the medicine's licence.
- 21.2 In order to prescribe medicines for 'off-label' use, you must ensure the following conditions are met:
 - o You are satisfied that it would better serve the patient's needs than an appropriately licensed alternative
 - You are satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy. Where the manufacturer's information is insufficient or of limited help, the necessary information must be sought from another reliable source.
 - You should explain to the patient/carer, in broad terms, the reasons why
 medicines are not licensed for their proposed use. If podiatrists intend to
 prescribe off label they are advised to obtain the written consent of the
 patient.
 - You make a clear, accurate and legible record of all medicines prescribed, and the reasons for prescribing an 'off label' medicine.
- 21.3 You may also, as a supplementary prescriber, prescribe a medicine for use outside the terms of its licence providing:
 - o There is a CMP in place, agreed in conjunction with the independent prescriber and with the consent of the patient and/or carer.
 - o The use of the medicines outside the terms of its licence is documented.
 - o The independent prescriber and the podiatrist supplementary prescriber take responsibility for prescribing the medicine and jointly oversee and monitor the patient's care and arrange for any follow-up treatment required.
- 21.4 Pharmaceutical companies do not usually test their medicines on children and consequently cannot apply to licence their medicines for use in the treatment of

- children. It is often necessary in paediatric practice to use medicines that are licensed only for adults. See the British National Formulary for Children.
- 21.5 It is good practice to give as much information to patients, or those authorising treatment of their behalf, as is required or which they may see as significant. This would include the proposed course of treatment, any known serious or common side effects or adverse reactions. Information must be given that is appropriate to the target audience (eg. children or those with learning difficulties).
- 21.6 Any information provided may be supported by written information, for example, the leaflet on unlicensed medicines produced by the Royal College of Paediatrics and the Child Health/Neonatal and Paediatric Pharmacists Group Standing Committee on Medicines.

Practice Guidance 22: Controlled Drugs

- 22.1 You may prescribe, supply and or administer Controlled Drugs by several mechanisms. A podiatrist independent prescriber may issue a valid prescription for those controlled drugs listed on their formulary. A podiatrist supplementary prescriber may prescribe any controlled drug where it is listed on the valid written clinical management plan agreed by a doctor. Controlled Drugs from Schedules 4 and/or 5 may be supplied and/or administered under the terms of a PGD but must not include anabolic steroids or the management of drug addiction.
- 22.2 If you are an independent prescriber, you may prescribe from a limited list of four controlled drugs:
 - Temazapam (oral)
 - Lorazapam (oral)
 - Diazepam (oral)
 - Dyhydrocodeine (oral)
- 22.3 You may have a need to use controlled drugs in settings and circumstances where patients are cared for as part of a medical Consultant-led team and/or where you have regular and on-going access to a Consultant. Examples include A&E and inpatient hospital settings for management of acute and pre/post-operative pain and out-patient hospital settings for chronic pain management⁴.
- 22.4 You must not prescribe a controlled drug for yourself.
- 22.5 You must not prescribe controlled drugs for someone close to you unless
 - No other prescriber is available to assess the patient's clinical condition and to delay prescribing would put the patient's life or health at risk, or cause intolerable pain.
 - You must be able to justify your decisions to prescribe controlled drugs for those close to you. You must record the nature of your relationship and the special circumstances that necessitated your action of prescribing controlled drugs to those close to you.
- You are required to know who your local Controlled Drugs Accountable Officer (CDAO) is and you must make contact with them and comply with local monitoring and/or inspection requests as necessary.
 Controlled drugs (supervision and management) regulations 2013
- 22.6 Standard Operating Procedures (SOPs) must be in place for the prescription of Controlled Drugs (CDs) according to Regulations, and should include procedures for:

⁴ In these settings the GP may be asked to provide the controlled drug on the recommendation of the secondary care team.

- o Prescribing CD's
- o Administering CD's
- Recording of any adverse reactions

Any SOP used must be validated by the organisation, follow the organizations' common template and must every stage of the CD journey from procurement (ordering, receipt, transport), safe storage, supply, administration, destruction and guidance for dealing with an incident.

- 22.7 Administration of CD's can be by any person acting in accordance with the valid instructions of the prescriber and in accordance with national guidance: Controlled drugs (supervision and management) regulations 2013
- 22.8 You must ensure that any prescription for a controlled drug is completed on the correct prescription form and contains all the required information commensurate with the Schedule of the drug being prescribed, including the patient's NHS number, or other unique identifier, in order for the prescription to be legally valid.
 - In-patient prescribing of CDs may be recorded on Medicines Administration Record or In-Patient medicines sheet in accordance with local polices.
 - CD's for patients being discharged may be written on locally approved TTO sheets.
 - Out-patient prescribing must be on the FP10PCD form
 - Out-patient prescribing by Supplementary Prescribers must be on the appropriate FP10SS form.
- 22.9 The validity of prescriptions for Schedule 2,3 and 4 drugs is limited to 28 days. The quantity of CD's prescribed must be commensurate with the clinical needs of the patient, but in all cases must be for no more than 28 days supply
- 22.10 You may use computer-generated prescriptions for controlled drugs, providing the necessary software is in place and that there is an audit trail of your prescribing practice.
- 22.11 Information for Prescriptions for CD's may be computer generated. Your signature must be hand written. Where patient-detail sticky labels are used, they must be tamper evident sticky labels and you must sign or initial over the sticky label to ensure the sticky label relates to the patient for whom your prescription is intended.
- 22.12 If any part of the CD prescription form is handwritten, this must be handwritten by you and not any other person.
- 22.13 Private prescription of CD's must include your unique 6-digit private prescriber code, which will be different from your unique NHS prescriber code. And this must be in knowledge of the AO for the geographical area you work in. (Prescribers who prescribe in both the NHS and privately will have therefore two different prescriber codes)
- 22.14 Patients should be encouraged to return all unwanted medicines to a pharmacy.

<u>Practice Guidance 23: Remote prescribing via telephone, email, fax, video</u> link, or website

23.1 From time to time, it may be appropriate to use a telephone or other non-face to face medium to prescribe medicines and treatment for patients/clients. Situations where this may occur include:

- o Where you have responsibility for the care of the patient.
- o When you are working in remote or rural areas.
- Where you have prior knowledge and understanding of the patient's condition and medical history
- o Where you have authority to access the patient's records and you are working within the scope of a supplementary prescriber, but the independent prescriber required to authorise the clinical management plan (CMP) works at a distance.
- 23.2 In all circumstances, you must ensure that you:
 - o Establish the patient's current medical conditions, history and concurrent or recent use of other medications, including non-prescription medicines
 - Carry out an adequate assessment of the patient's condition (in line with practice quidance 3)
 - o Identify the likely cause of the patient's condition
 - Ensure that there is sufficient justification to prescribe the medicines or treatment proposed. Where appropriate you should discuss other treatment options with the patient
 - Make a clear, accurate, legible and contemporaneous record of all medicines prescribed
- 23.3 Where you cannot meet all of these requirements you must not use remote means to prescribe medicines for a patient.

Practice Guidance 24: Mixing

Licensed medicines are rendered unlicensed if they are mixed together prior to administration. The law defines 'mixing' as the combination of two or more licensed medicines together for the purposes of administering them to an individual patient.

- 24.1 If you are a podiatrist independent prescriber you may mix medicines prior to administration.
- 24.2 If you are a podiatrist supplementary prescriber, you may mix medicines that are defined within a written CMP.
- 24.3 You must not mix controlled drugs prior to administration to the patient.
- 24.4 You must only mix medicines according with relevant national and local guidelines. Before mixing medicines, you should
 - Be satisfied that an alternative, premixed and/or licensed product would not meet the patient's needs.
 - Be satisfied that there is a sufficient evidence base for mixing the medicines to demonstrate safety and efficacy.
 - Record the medicines prescribed and the reasons for mixing them product in the patients notes.
- 24.5 Mixing of medicines must only occur for the identified benefit of patients. You must not mix medicines solely for your own convenience.

Practice Guidance 25: Prescribing on the recommendation of others

25.1 You should only prescribe for patients on your own caseload/under your overall care. You cannot prescribe for any patients upon whom you have not undertaken an appropriate assessment. You must not prescribe for a patient unknown to you simply because you are the only prescriber available, except in an absolute emergency where the patient's life is in imminent danger.

- 25.2 The conditions for non-medial independent prescribing are not the same as for medical prescribing. If you prescribe on the recommendation of another health professional, who does not have prescribing rights, you must satisfy yourself that you have performed an appropriate assessment of the patient yourself in order to reach a diagnosis in order to determine if the prescription request is appropriate for the patient concerned and that the professional is competent to have recommended the medication.
- 25.3 You do not necessarily have to conduct a face to face consultation with the patient, but you must ensure that have performed an appropriate assessment in order to gain enough sufficient information upon which to make your prescribing decision. Where you cannot satisfy yourself of this, you should not prescribe on the recommendation of others.

Practice Guidance 26: Simultaneous prescribing and dispensing

26.1 It is recommended where possible that this does not occur although it is accepted that under the current exemption provision for Podiatrists this is common practice. It is appreciated there are some clinical situations (such as treatment with injectable depo-medrone) where the decision, supply & administration is undertaken without direct involvement with a dispenser. The guidance would instruct, however, that this is not a standard or accepted practice for the future Independent Prescribing practitioner of the majority of medicines.

Practice Guidance 27: Antimicrobial prescribing

- 27.1 You should apply local and national policies, procedures and guidelines relevant to infection control in your prescribing practice.
- 27.2 You should implement work practices that reduce the risk of infection and follow infection control protocols relevant to your area of work.
- 27.3 You should follow local and national approaches to support optimal prescribing of antimicrobials and manage antimicrobial resistance.
- 27.4 You should ensure you have considered reasonable self-management strategies relevant to the treatment of self-limiting conditions before prescribing antibiotics.
- 27.5 You should discuss common side effects associated with commonly administered antibiotics.
- 27.6 You should record any patient allergy to antibiotics in the patient record.
- 27.7 Before prescribing antibiotics, you should consider whether prescribing is necessary at the point in time of if delayed prescribing is more appropriate.
- 27.8 You should ensure the dose, timing and route of antibiotic that you prescribe is appropriate for the patient and condition being treated.
- 27.9 You should understand the circumstances where it may be necessary to switch from intravenous to oral routes of antibiotic prescribing.
- 27.10 You should discuss patient/carer expectations and/or demands for antibiotic prescribing and ensure that you only prescribe antibiotics when clinically indicated.
- 27.11 You should understand the antimicrobial treatment policy decisions in your area of work and ensure that you participate in multi-professional prescriber networks to ensure that antibiotics are prescribed appropriately.

Section (3) - Medicines Governance

Practice Guidance 28: Prescribing and administration/supply

- 28.1 If you are an independent or supplementary prescriber and you hold a POM certificate (ie you possess the POM annotation on the HCPC register), you must ensure a separation of prescribing and administering activities whenever possible. You must be clear whether you are prescribing a medicine as an independent or supplementary prescriber or supplying/administering a medicine from the podiatrists' exemption lists.
- In exceptional circumstances where you are involved in both prescribing and administering a patient's controlled drug, a second suitably competent person should be involved in checking the accuracy of the medication provided.

Practice Guidance 29: Prescribing and dispensing drugs

- 29.1 Dispensing is the preparation and supply of a medicinal product by a practitioner in accordance with a prescription. This is usually supervised by a pharmacist.
- 29.2 You must ensure a separation of prescribing and dispensing whenever possible.
- 29.3 Podiatrists must ensure they have indemnity insurance to cover the prescribing and dispensing of drugs.

Practice Guidance 30: Dispensing

- 30.1 Dispensing of a prescription is part of the remit of the pharmacy profession, whose practitioners undertake a clinical screen of prescriptions prior to dispensing by trained technicians, and a final accuracy check by a pharmacist or higher-level pharmacy technician.
- 30.2 Podiatrists should not dispense medicines unless there is a local policy in place, agreed by clinical governance directorates to endorse to podiatrist's actions. A podiatrist should not normally dispense against a prescription that they have issued.
- 30.3 The recipient of the medication will expect the same level of practice from a podiatrist as they would from a pharmacist. As a podiatrist you are accountable for your actions and should understand the medication that you are dispensing, its therapeutic effect, correct dosage, side effects and contraindications. You should be able to inform the patient about what they should expect when taking the medication and to whom any adverse reaction should be reported.
- 30.4 You should only dispense medication if you feel competent to do so, and in the knowledge that you are accountable for your actions. A record should be kept of your dispensing practice. Following clinical governance policy, you should ensure that an audit trail is present and visible.
- 30.5 The same principles apply for all drugs, whether they are prescription only medicines or pharmacy only medicines. It is recommended that podiatrists ensure that they are covered for vicarious liability (if appropriate) and seek appropriate indemnity insurance for this practice.
- 30.6 See the Glossary for a definition of dispensing.

Practice Guidance 31: Storage

- 31.1 You should ensure all medicinal products are stored in accordance with the information within the Summary of Product Characteristics/Patient Information Leaflet or information found on the label.
- When not in use, medicines should be stored in lockable containers or cabinets or otherwise returned to a Pharmacy department for safe-keeping.
- 31.3 You must not store medicines at home unless your home is also your designated workplace. You must have the written permission of your employer to do this, which describes the exceptional circumstances that require you to store medicines in your home and you must have suitable lockable storage facilities in place.
- 31.4 All storage environments must meet the prevailing storage requirements and it is your responsibility to find out what these requirements are. You must ensure correct storage polices are in place and are being adhered to.

Practice Guidance 32: Transportation

- You may transport medicines from the dispensing pharmacy to their place of use. You must display appropriate health and safety information on your vehicle if the medicine requires it e.g. medical gases.
- 32.2 You should not leave medicines unattended in your vehicle at any time.

Practice Guidance 33: Disposal

- 33.1 You must dispose of used, partially used and unused medicines in accordance with current legislation and your local employer policy.
- 33.2 If there is no local employer policy in place, you should return all medicines to a Pharmacist for safe disposal.

Practice Guidance 34: Error Reporting

- 34.1 If you discover that you have made an error in prescribing you must take immediate action to prevent potential harm to the patient and you must report the error as soon as possible according to local protocols.
- 34.2 If you think there is an error in a prescription that has been written and/or dispensed by someone else, you must seek clarification of the prescriber's wishes before administering the medicine. You should also report the error according to local protocols.

Practice Guidance 35: Reporting Unexpected Effects and Adverse Reactions

- 35.1 If a patient experiences an adverse reaction to a medication they have been prescribed, you should record this in the patient notes, notify the prescriber (if you did not prescribe the drug) and notify the MHRA via the Yellow Card Scheme immediately. Yellow cards are found in the back of the British National Formulary and also online at www.yellowcard.gov.uk.
- 35.2 You may also inform the patient that they can report adverse reactions independently to the Yellow Card Scheme.
- 35.3 You must also report adverse reactions via the Medicines and Healthcare Products Regulatory Agency (MHRA) website at www.mhra.gov.uk and any untoward incidents are also reported to the National Patient Safety Agency (NPSA).

Practice Guidance 36: Complementary Medicinal Products

- 36.1 Podiatrists need to be familiar with a range of complementary medicinal products that their patients or clients may be using, or may wish to be used, in their treatment. Podiatrists are responsible for checking for possible interactions prior to prescribing or administering any medicines.
- 36.2 Herbal Medicines: There are presently three regulatory categories of herbal medicines: unlicensed herbal remedies, registered traditional herbal medicines and licensed herbal medicines. Unlicensed herbal remedies are products which do not meet specific standards of safety and quality. From April 2011, all manufactured herbal medicines will be required to have either a traditional herbal registration or a product licence. Registered traditional herbal medicines are products which are required to meet specific standards of safety and quality. Licensed herbal medicines are products that hold a marketing authorisation (product licence) and are required to demonstrate safety, quality and efficacy. For further details the MHRA website should be consulted, at:

http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicines/index.htm

In particular, attention should be paid to the section on Traditional Chinese Medicines:

http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicines/Herbalsafetyadvice/TraditionalChinesemedicines/index.htm

Homeopathic Medicines: a homeopathic medicinal product is defined in European legislation Article 1(5) of Directive 2001/83/EC as amended by 2004/27/EC as 'any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeia currently used officially in the Member States'. Presently homeopathic medicines are registered under the Simplified Scheme (1992) or the National Rules Scheme (2006). The Simplified Scheme requires that safety and quality of the products must be demonstrated but does not permit products to make therapeutic claims. The National Rules Scheme enables homeopathic medicines to be registered with indications (the description of diseases or conditions for which the medicine is intended to be used) for the relief or treatment of minor symptoms and conditions (those that can ordinarily be relieved without the supervision of intervention of a doctor). For further details the MHRA website should be consulted, at:

http://www.mhra.gov.uk/Howweregulate/Medicines/Homeopathicmedicines/index.htm

Section (4) - Clinical Governance

Patient safety is of paramount importance within all aspects of prescribing and medicines management. Podiatrists must practice within the law, to a high professional standard, and ensure that they strive continuously to improve the quality of care that they offer to patients. Poor professional performance needs to be identified and rectified at an early stage. Podiatrists who are working within the NHS are likely to be covered by appropriate clinical governance protocols and procedures. These will include prescribing analysis and clinical audit. Podiatrists who are prescribing outside the NHS should ensure that they have appropriate clinical governance measures in place.

Arrangement should be made for:

o Clear lines of responsibility and accountability for overall quality of clinical care.

The development of quality improvement programmes, such as clinical audit, supporting evidence-based practice, implementation of clinical standards, monitoring of clinical care, access to appropriate CPD programmes, and the management of risk and procedures to identify and remedy poor performance.

Practice Guidance 37: Clinical Audit

- 37.1 Clinical audit is an important part of clinical governance, as it helps podiatrists to monitor their prescribing activities. The College of Podiatry PASCOM-10 system may be considered for use as an audit tool for the collection of data on prescribing activity, for both independent and supplementary prescribing (as well as the supply, sale and administration of medicines via other routes, such as via exemption lists, Patient Group Direction or Patient Specific Direction). Audit data might include not only numbers of patients treated, but also information on patients treated by a podiatrist who might otherwise have been referred to a medical practitioner. Please note that the PASCOM-10 database is available only to members of the College of Podiatry.
- Where not accessible to non-members of the College of Podiatry it is advised that an equally robust method of audit and recording is in place to help inform and reflect on prescribing patterns and outcomes.
- 37.3 Podiatrists who are supplementary prescribers should ensure that they participate in regular (normally at least annual) meetings with their independent prescriber.
- 37.4 Podiatrists should audit how many of the patients for whom they have prescribed medication have required medical follow-up, and how many have been successfully managed within the podiatry practice.
- 37.5 Podiatrists should monitor how patients respond to their treatment and how many follow-up visits are taking place. Systems should be put in place to ensure that patients who do not attend ('DNA') for their appointments are followed up (eg. by telephone, letter, text message or email).
- 37.6 Podiatrists who are working as supplementary prescribers should audit their practice to ensure that the provisions of the CMP are being followed.
- 37.7 Podiatrists should ensure that the prescriptions they write are clear and legible. Podiatrists should audit how many times a pharmacist contacts the podiatrist to query what was written.
- 37.8 Podiatrists should also audit how often they supply a prescription only medicine (if they are entitled to do so) to a patient, rather than writing a signed order or prescription for the pharmacist to supply the medicine.
- 37.9 Podiatrists should also audit their record keeping ensuring that all the pertinent details are included contemporaneously.
- 37.10 Patient's experiences of podiatric prescribing are an important part of clinical care and should be regularly sought.

Practice Guidance 38: Prescribing analysis and evidence-based practice

38.1 Podiatrist prescribers should ensure that they have information about national guidelines (eg. NICE guidelines, National Service Frameworks), local guidelines, local agreements and formularies.

38.2 If podiatric prescribing is within the NHS it should be included in the reports on the quality of clinical care submitted to local Clinical Governance Committees or their equivalent.

Practice Guidance 39: Risk Management - Learning from incidents and errors

- 39.1 Podiatrists should ensure that they have an appropriate Risk Management programme in place. This would include clinical risk management and patient safety (including the NPSA National Reporting and Learning Scheme, or equivalent), confidentiality, safety of prescription pads and a system for handling and managing complaints.
- 39.2 All incidents and errors should be recorded on the local incident reporting system to facilitate national reporting. All incidents and errors should be scored, and the total number of low and high scoring incidents tracked as a performance measure Incidents should be shared within the multidisciplinary team to enable learning and where necessary changes in practice.

Practice Guidance 40: Continuing Professional Development

- 40.1 It is your responsibility to remain up to date with appropriate knowledge and skills to enable you to prescribe competently and safely.
- 40.2 You should ensure that your CPD is in line with your role as a prescriber.
- 40.3 You should record your CPD in a format that easily enables you to demonstrate your fitness to practice as a prescriber.
- 40.4 You should ensure that you set aside enough time to assess programmes and resources to meet your CPD needs. This may include Peer Review sessions. Podiatrists should include reflective learning in their CPD portfolio.

Practice Guidance 41: Poor Performance

41.1 Procedures should be put in place for identifying poor professional performance, including that of podiatrist prescribers. This could be via peer review processes or pharmacist/medical practitioner feedback. The National Clinical Assessment Service (NCAS) has published several documents relating to performance issues, which offer templates. Although the NCAS service is only available for doctors and dentists, the principles are applicable to other healthcare professionals, including podiatrists. Further information is available at: www.ncas.npsa.nhs.uk under 'key publications' and 'toolkit'.

Practice Guidance 42: NHS Prescription Pads

- 42.1 NHS prescription forms are classed as secure stationery. Each prescription has a serial number and has specific anti-theft and anti-forgery features. Prescription pads will be ordered by the NHS employing organisation via a secure ordering system and supplied to the named professional they relate to.
- 42.2 You are responsible for the safety of your named prescription pad. You must take all reasonable and responsible steps to prevent its loss or inappropriate use. You should only use one prescription pad at a time.
- 42.3 You should keep a record of the first and last serial number of the prescriptions in the pads issued to you. If a whole prescription pad is lost or stolen, you must report

- the serial numbers of the missing prescriptions to the local clinical governance committee and complete the local trust required paperwork
- 42.4 At the end of each working day you should record the serial number of the first remaining prescription in your current pad. If your current pad is lost or stolen after you last used it, the relevant serial number of unused prescriptions must be reported to the local clinical governance committee and complete the local trust required paperwork
- Prescription pads should be stored in locked areas when not in use. You should not store prescription pads away from your place or work. In particular you should not store pads at home or in your vehicle except when travelling between places of work.
- 42.6 Detailed Guidance can be found in 'NHS Security Management Service- Security of Prescription Forms Guidance August 2013.

Practice Guidance 43: Gifts and benefits

- 43.1 You must make your choice of medicinal product for the patient based solely on clinical suitability and cost effectiveness.
- 43.2 You must maintain a 'register of interest' within your own personal portfolio, which may be produced on request if required for audit purposes.
- 43.3 You should adhere to local corporate policy when maintaining a 'register of interests.
- 43.4 The advertising and promotion of medicines is strictly regulated under the Medicines (advertising) Regulations 1994. Personal gifts are prohibited, and it is an offence to solicit or accept a gift or inducement. Companies may offer hospitality for a professional/scientific meeting, but such hospitality must be reasonable in level, and subordinate to, the main purpose of the meeting. This legislation is enforced by the Medicines and Healthcare Products Regulatory Agency.
- The NHS may have a local policy on sponsorship and gifts from pharmaceutical companies. Such a policy may serve as useful guide as to whether it is appropriate to accept a benefit offered by a pharmaceutical company.

<u>Practice Guidance 44: Links with Pharmaceutical Companies /</u> Conflict of interest

- 44.1 If you have a commercial or financial interest in any pharmaceutical product or company then you should ensure that your patients have access to this information where relevant and you should ensure that your interest does not affect your ability to prescribe in the patient's best interest alone.
- 44.2 You must not allow your own, or your employer's (if applicable) commercial or financial interests in a pharmaceutical company or product influence the way you advise your patients.
- 44.3 You must maintain a 'register of interests' either within your personal portfolio, or within your employers Hospitality Register which should be produced on request for audit purposes.

Practice Guidance 45: NHS/ Private Practice Prescribing boundaries

45.1 You must not ask the patient's GP to prescribe medicines at NHS expense which Subsequently are to be administered as part of private healthcare provision. If you do ask a GP to do this, they are within their rights to refuse to do this.

Glossary of Terms

Term	Definition
Clinical Governance	Quality Assurance activities which ensure
omnour covernance	that pre-determined clinical standards that
	have been set are seen to be maintained by
	practitioners and are evidenced within
	healthcare settings.
Clinical Management Guidelines (CMGs)	CMGs are produced by the College of
Chinear Management Guidennes (CMG3)	Podiatry and represent a reliable source of
	evidence-based information about the range
	of medicines used in podiatric practice.
Clinical Management Plan (CMP)	The CMP is the foundation stone of
Chilical Management Flan (CMF)	supplementary prescribing. Before
	supplementary prescribing can take place, it
	is obligatory for an agreed CMP to be in
	place relating to a named patient and to
	that patient's specific condition(s) to be
	managed by the supplementary prescriber.
	Required information includes details of the
	illness or conditions that may be treated,
	the class or description of medicinal
	products that can be prescribed or
	administered, and the circumstances in
	which the supplementary prescriber should
	refer to, or seek advice from, the
	independent prescriber. It is an agreement
	between the independent and
	supplementary prescriber and is made with
	the consent of the patient or a person
	responsible for the patient. Supplementary
	prescribers must have the same access to
	the same patient health records as the
	independent prescriber.
Commissioners	Those funding the programme, such as:
Commissioners	Primary Care Trust or Practice Based
	Commissioning Groups (England), Local
	Health Boards (Wales) Scottish Executive
	Health Department and the Department of
	Health and Social Services and Public Safety
	(Northern Ireland).
Competence	Relates to the need for the student to
Competence	demonstrate their 'capability' in certain
	skill areas to a required standard at a given
	point in time.
Competencies	Component skills which contribute to being
Compotentia	competent and achieving the standards of
	proficiency for registration. Competencies
	might include skills arising from learning
	outcomes or other requirements.
	outcomes of other requirements.
Designated Medical Practitioner	Identified named medical practitioner who
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Dispensing (of medicines)	provides supervision and support to podiatrist prescribers, assesses their application of theory to practice and signs off satisfactory completion of the period of learning and assessment in practice. To label from stock and supply a clinically appropriate medicine to a patient/carer, usually against a written prescription, for self-administration or administration by another professional, and to advise on safe
Independent Prescribing	and effective use. A practitioner (eg. a doctor, dentist, nurse, pharmacist, optometrist, physiotherapist, therapeutic radiographer, paramedic or podiatrist) who is responsible and accountable for the assessment of patients with undiagnosed or diagnosed conditions and for decisions about the clinical management required, including prescribing. Within medicines legislation the term used for these practitioners is 'appropriate practitioner'.
Licensed Medication	The Medicines and Healthcare Products Regulatory Agency (MHRA) operates a system of licensing before medicines are marketed (see marketing authorisation). However, the Human Medicines Regulations 2012) allows certain exemptions from licensing which include: • The manufacture and supply of unlicensed relevant medicinal products for individual patients (commonly known as 'specials') • The importation and supply of unlicensed relevant medicinal products for individual patients • Herbal remedies exemption.
Marketing Authorisation	Previously known as a 'Product Licence'. This normally must be granted by the MHRA before a medicine can be prescribed or sold. This authorisation, which confirms that medicines have met standards for safety, quality and efficacy, considers all the activities associated with marketing medicinal products.
Medicines Act Exemptions	Allow certain groups of healthcare professionals, including podiatrists, ambulance paramedics, midwives and optometrists, to sell or supply medicines directly to patients, or to administer certain POM medicines to patients. Provided the requirements of any conditions attached to those exemptions are met, a Patient Group Direction is not required.

Medicines and Healthcare Products	The MHRA is a government body, set up in
Regulatory Agency (MHRA)	2003, which brings together the functions of the Medicines Control Agency and the Medical Devices Agency. It is the government agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe.
'Off Licence'	The use of a medicine outside the terms of its licence (also called 'off-label'). This should not be confused with unlicensed medicines.
Patient Group Directions	A written instruction for the supply or administration of named medicines to specific groups of patients who may not be individually identified before presenting for treatment. Guidance on the use of PGDs is contained within Health Service Circular (HSC) 2000/026. The circular also identifies the legal standing of PGDs plus additional guidance on drawing them up and operating within them. It is vital that anyone involved in the delivery of care within a PGD is aware of the legal requirements. It is not a form of prescribing. See also guidance at: www.npc.co.uk/publications/pqd/pdf
Patient Specific Directions	A Patient Specific Direction is the traditional written instruction, from a doctor, dentist, nurse, pharmacist, optometrist, physiotherapist or podiatrist independent prescriber for medicines to be supplied or administered to a named patient. In primary care, this might be a simple instruction in the patient's notes, or in secondary care it might take the form of instructions recorded on a patient's ward drug chart.
Register of Interests	Prescribers are required to keep a 'register of interests' that they may have that could impact on their prescribing practice. For example links with pharmaceutical companies, pharmaceutical company sponsorship of events, gifts received etc.
Repeat Prescription	A partnership between patient and prescriber that allows the prescriber to issue duplicate prescriptions at agreed intervals, without the patient having to consult the prescriber at each issue.
Repeatable Prescription	A prescription which authorises a pharmacist to issue it more than once (for example, to supply a given medication every month for six months).
Supplementary Prescribing	A voluntary partnership between an independent prescriber and a supplementary prescriber to implement an agreed patient-specific clinical management plan with the patient's agreement.

Unlicensed Medicines	 Medicines that are not licensed for any indication or age group. Reasons why a drug may not be licensed include: The drug is undergoing a clinical trial, has been imported, has been prepared extemporaneously, or prepared under a special manufacturing licence. The product is not a medicine but is being used to treat a medical condition. The MHRA may consider an agent to fall into this category if does not have a primary mode of action that is metabolic, immunicological or pharmacological in effect.
Yellow Card Scheme	If a patient experiences an adverse drug reaction to a medication the podiatrist should record this in the patient notes, notify the prescriber (if they did not prescribe the drug) and notify the MHRA via the Yellow Card Scheme immediately. Yellow Cards are found in the back of the British National Formulary, and online at www.yellowcard.gov.uk . For further information consult the BNF or access the MHRA website www.mhra.gov.uk .

<u>Legal Classification of Licensed Medicines</u>

Prescription Only Medicines (POM)	POMs require a prescription to be written, usually by a doctor, dentist, nurse, pharmacist, optometrist, physiotherapist, podiatrist or other approved prescriber. POMs are subject to the additional requirement that they are sold or supplied in accordance with an appropriate practitioner's prescription. An 'appropriate practitioner' is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber, optometrist independent prescriber, physiotherapist independent prescriber, podiatrist independent prescriber, independent prescriber prescriber independent prescriber, independent prescriber radiographer, independent prescriber paramedic or a supplementary prescriber.
Pharmacy Only Medicines (P)	P medicines can only be sold through a registered pharmacy by or under the personal supervision of a pharmacist (ie the pharmacist needs to be present before a P medicine can be sold).
General Sales List Medicine (GSL)	GSL medicine can be sold in general shops as well as through pharmacies, albeit often in small quantities. All of the products are sold in the original manufacturer's packs. All packaging must be intact.
Over the Counter medicines (OTC)	Not a legal classification, but a generic term that covers both P and GSL medicines.
Note:	Where the same drug is available in more than one legal classification, for example where it is available in both P and POM forms, the licensed indications for its use may differ.

Resources

Clinical Knowledge Summaries are a reliable source of evidence-based information and practical 'know how' about the common conditions managed in primary care, providing quick answers to real life questions that arise in the consultation' For further information see http://cks.nhs.uk/home.

The Department of Health website at: www.dh.gov.uk/nonmedicalprescribing.

The MHRA website contains information about the legal framework governing the prescribing, supply, sale and administration of medicines at: www.mhra.gov.uk.

The Medicines Partnerships Programme at www.medicines-partnership.org.

The National Clinical Assessment Service at: www.ncas.npsa.nhs.uk.

The National Prescribing Centre produces useful information including competency frameworks, guides to practice and resources to help healthcare professional understand prescribing matters. The NPC also organises study days and conferences to update practitioners. The web address is: www.npc.co.uk.

The National Electronic Library for Medicines includes a webpage on Patient Group Directions on which a centrally maintained archive of approved PGDs can be found. Visit: www.druginfozone.org.uk.

For members of the College of Podiatry, useful webpages are to be found at the 'Medicines' section: http://www.members.feetforlife.org/cgi-bin/item.cgi?ap=1&id=2110&d=pnd&dateformat=%25o-%25B.

The Allied Health Professions Federation website hosts the outline curriculum framework for AHP supplementary and Independent Prescribing courses, which is a generic resource and guidance for Higher Education Institutions when developing IP and SP courses: http://www.ahpf.org.uk/

The Health and Care Professions Council sets the standards expected of podiatrists which can be found at: http://www.hcpc-uk.org/aboutregistration/standards

The Royal Pharmaceutical Society of Great Britain (RPSGB) provides a webpage with a search facility on the legal classification of medicines at: http://www.rpsgb.org.uk/worldofpharmacy/useofmedicines/searchlegalclassificationofmedicines.html

The British National Formulary online is available at: http://bnf.org/bnf/

The electronic medicines compendium is available at: http://www.medicines.org.uk/emc/

The College of Podiatry would like to acknowledge the following sources which helped provide a template for, and have informed the writing of, this guidance document:

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