Health Professions Council
Education and Training Committee, 28th March 2007

Approval of programmes leading to entitlements under the Prescription Only Medicines (Human Use) Order 1997

Executive Summary and Recommendations

Introduction

The attached paper makes recommendations about, and relevant to, the approval of programmes leading to entitlements under the Prescription Only Medicines (Human Use) Order 1997.

Decision

The Committee is invited to agree the recommendations at points 1 to 8 in the paper, and recommend approval by the Council.

Background information

None

Resource implications

None

Financial implications

None

Background papers

None

Appendices

Appendix 1: List of medicines which can be sold, supplied or administered by chiropodists who have their names annotated on the register.

Appendix 2: Outline Curriculum for Training Programmes to prepare Allied Health Professional Supplementary Prescribers (Department of Health and National Prescribing Centre, 2004).

Appendix 3: Draft plan of activities

Date of paper
16th March 2007

Approval of programmes leading to entitlements under the Prescription Only Medicines (Human Use) Order 1997

Section 1: Local Anaesthetics and Prescription Only Medicines

Introduction

We currently annotate the register to indicate where registrant chiropodists and podiatrists are qualified to administer local analgesia ("LA") and to supply prescription only medicines ("POM") under the Prescription Only Medicines (Human Use) Order 1997.

All the pre-registration podiatry programmes we currently approve include modules which cover these two areas. Students successfully completing these programmes can be registered in the relevant part of the register, with these entitlements annotated.

We currently approve three post-registration programmes which allow registrants who do not have the entitlement in local anaesthetics to achieve this. The programmes are run by New College Durham, Anglia Ruskin University and Glasgow Caledonian University. We do not currently approve any post-registration programmes in the use of prescription only medicines.

Legislative background

The Medicines Act 1968 regulates the administration, sale and supply of all medicines available in the UK.

The Prescription Only Medicines (Human Use) Order 1997 establishes classes of medicines and specifies appropriate practitioners for sale, administration and supply. This includes the ability of certain professions to supply and administer via a patient group direction and supplementary prescribing rights. The order is regularly amended to extend rights to different professionals and extend the list of drugs which certain professions can administer or supply on their own initiative.

The 1997 order gave state registered chiropodists the legal entitlement to administer certain local anaesthetics within the course of their practice without a prescription from a doctor, providing they held a 'certificate of competence' in the use of analgesics issued by the Chiropodists board of the CPSM. An amendment to the order in 1998 gave state registered chiropodists who held a certificate of competence in their use to supply certain prescription only medicines in the course of their professional practice. Subsequent amendments have since removed reference to the state register maintained by the CPSM.

Rule 6 (2) The Health Professions (Parts and entries in the register) Rules Order of Council 2003 states that where a chiropodist holds a certificate of competence issued by the Health Professions Council the Register may indicate that he holds such a certificate.

Most recently, The Medicines for Human Use (Administration and Sale or Supply) (Miscellaneous Amendments) Order 2006 amended the Prescription Only Medicines order, extending the range of medicines which chiropodists with relevant annotation(s) could administer and supply. The order also amended the wording to remove reference to the certificate of competence. The relevant exemptions now read that they are available to 'Registered chiropodists against whose names are recorded in the relevant register annotations signifying that they are qualified to use the medicines specified…'.

Appendix 1 is a up-to-date list of all the medicines which can be administered, sold or supplied by chiropodists and podiatrists with the relevant annotation(s).

Existing registrants

Some registrants who were registered prior to local anaesthetic and prescription only medicines entitlements becoming a standard part of pre-registration education and training, some international registrants and those who were registered under grandparenting and could not previously access these entitlements, do not currently have entitlements. Some of those successful registered may not have either entitlement.

For registrants who already have these entitlements, the range of medicines which can be administered and supplied has been extended. Such registrants, in accordance with the standards of conduct, performance and ethics, would need to ensure that they have the appropriate knowledge and skills before using the new drugs in their practice. Although they might wish to do so to update their skills, they would not need to undertake a programme approved by HPC to do so. However, they would need to ensure that they were capable of using these drugs safely and effectively and this might include undertaking CPD activity in this area.

Approval of local anaesthetics and prescription only medicines modules / programmes

At present, should an education provider wish to offer a standalone programme in local anaesthetics or prescription only medicines, they would need to seek separate approval. This would entail a separate approvals visit and assessment against all the standards of education and training (excluding SET 1: Level of qualification of entry to the Register[1]).

We have received feedback directly from education providers and via the Society of Chiropodists and Podiatrists that this arrangement is acting as a barrier to education providers. In particular, a small number of education providers have suggested that they would like to accept registrants who do not have the entitlements directly on to modules leading to the POM entitlement which they already run as part of pre-registration programmes, but are unable to do so because of the burden of present approval arrangements.

[1] This was agreed by the Education and Training Committee on 16th February 2005: http://www.hpc-uk.org/assets/documents/100006C4education_and_training_committee_20050216_enclosure08.pdf.

Many education providers had not previously run prescription only medicines programmes because the entitlements were only available to state registered podiatrists who had covered this in their pre-registration training. However, a significant number of registrants who registered via grandparenting and some via the international route do not have this entitlement. Further, the extension of the range of medicines available under the POM entitlement makes this a more attractive programme to run.

In pre-registration programmes, the LA component is normally taught as an integral part of the programme, forming an integral part of the placements throughout the programme. In contrast, the POM component is normally taught as a separate, self-contained module. Therefore, whilst it is possible for a POM module to be run separately, the same is not true for the LA component.

The Executive proposes that POM modules which form part of pre-registration programmes which have been approved, should be separately approved as sufficient for the register to be annotated, subject to an additional paper based assessment.

The Executive suggests that, in order for the Council to be satisfied for modules to run as 'stand-alone' programmes leading to the annotation, they should be additionally assessed against SET 2: Programme Admissions. This will ensure that the education provider has appropriate selection and entry criteria for direct entry into the module, including ensuring that students have appropriate prior knowledge and skills. The remaining SETs would have been met as part of the approval, and ongoing monitoring, of the pre-registration programme.

The assessment should be paper based and carried out remotely by two visitors, in the same way as annual monitoring and major/minor change information is considered. At least one of the visitors should be from the relevant part of the profession with the POM entitlement. The recommendation of the visitors would then be considered by the Education and Training Panel for formal approval.

The Committee is invited to agree and recommend to the Council:

1. that modules leading to the prescription only medicines entitlement (POM) which form part of already approved pre-registration chiropody and podiatry programmes can be separately approved for the purposes of entitlements under the Prescription Only Medicines (Human Use) Order 1997, subject to a paper-based assessment by two visitors against SET 2 of the standards of education and training; and that
2. programmes which do not form part of approved pre-registration programmes will require a separate visit (as present).

If agreed by the Committee, the Council would be asked for approval at their meeting on 31st May 2007 and the change would be effective of this date. The education: approvals and monitoring department would inform all education providers offering pre-registration programmes, and those education providers who have previously contacted us about offering POM programmes, of the new arrangements.

Section 2: Standards for post-registration entitlements

Introduction

In addition to entitlements for local anaesthetics and prescription only medicines, the Council currently approves post-registration programmes in supplementary prescribing and annotates the Register to indicate where the entitlement is held. The professions who are able to undertake supplementary prescribing are chiropodists and podiatrists, physiotherapists and radiographers.

Standards of proficiency

Standard of education and training 4.1 says that:

"*The learning outcomes must ensure that those who successfully complete the programmes meet the standards of proficiency for their part of the Register.*"

- Local Anaesthetics and prescription only medicines

There are two standards in the existing standards of proficiency for chiropodists and podiatrists which relate to prescription only medicines and local anaesthetic entitlements. They are:

- *administer relevant prescription only medicines, interpret any relevant pharmacological history and recognise potential consequences for patient treatment. This standard applies to registrants who wish to be certified as competent under the Medicines Act 1968 by the HPC* (Standard 2b.4).

- *apply local anaesthesia techniques. This standard applies only to registrants who wish to be certified as competent under the Medicines Act 1968 by the HPC* (Standard 2b.4).

These standards do not provide detailed learning outcomes for the safe and effective practice of each of these disciplines. Presently, when modules in these disciplines and stand-alone programmes in local analgesia are approved, the visitors make a judgement about whether one standard of proficiency has been met, taking into account the Curriculum guidance, if relevant. The Executive suggests that it would be helpful for the Council to produce learning outcomes relating to these areas which could be a basis for ensuring safe and effective practice.

The Health Professions Order 2001 permits the Council to produce separate standards of education and training for additional qualifications or entitlements that it wishes to record on the Register. However, the Order does not strictly provide for separate standards of proficiency for such entitlements. Article 5 (2) (a) refers to standards of proficiency necessary for admission to each part of the register, rather than necessary for annotations of that part of the register.

The Executive has sought advice on this issue and proposes that separate 'competencies' should be produced for each of these areas. These competencies would outline the standards that it is necessary to achieve in order to have the Register annotated as sufficient to administer local anaesthetics or supply prescription only medicines under the relevant legislation.

The Committee is invited to agree and recommend to the Council:

3. that separate competencies should be written for threshold safe and effective practice in local anaesthetics and prescription only medicines. Pre-registration programmes would be assessed against these learning outcomes. Stand alone programmes in these areas would also be assessed against the relevant competencies.

These components are also currently optional in the standards. This reflects that a significant minority of registrants will have trained prior to LA and POM becoming a standard part of pre-registration education and training. It also reflects that applicants applying to the Council under the grandparenting arrangements which ended in July 2005 would not have been able to meet these standards.

During the recent review of the standards of proficiency, the Society of Chiropodists and Podiatrists suggested that as local anaesthetics and prescription only medicines are now a standard part of pre-registration education and training it was no longer necessary for these standards to be optional. At that time we sought legal advice which suggested that the standards should continue to remain optional at this time. One particular issue was how we would be able to deal with applications from applicants who had trained overseas if the standards were no longer optional.

Overseas applicants are assessed by two assessors against the full standards of proficiency for chiropody and podiatry. The annotations for local anaesthetics and prescription only medicines are awarded on recommendation of the assessors following scrutiny of the application. However, for some applicants these areas do not form a standard part of podiatry practice in their home countries and therefore they are not able to meet the standards in these areas.

Since the opening date of the register in 2003 the following international applicants have been registered:

- 112 have been registered with LA only
- 14 have been registered with both entitlements
- 0 applicants have been registered with POM and not LA
- 39 applicants have been registered without either entitlement

The Executive has discussed the issues with the Council's legal advisor who has advised that should the Committee agree that these areas are an integral part of the safe practice of chiropody and podiatry, it would be reasonable to removal the standards' optional status. The consequences of the existing standard and the suggested removal of the optional status is shown below.

The existing situation:

- Applicants via the international route can be registered with both entitlements, with one of the entitlements, or no entitlements, following assessment and recommendation by registration assessors
- All pre-registration chiropody and podiatry programmes include both entitlements. However, as the standards are optional, it is possible that an education provider could approach us to deliver their programme without them.

If the 'optional' part was removed:

- Applicants via the international route would not be registered unless they could demonstrate that they met all of the standards of proficiency, including the standards relating to POM and LA.
- All pre-registration programmes would need to include both entitlements, otherwise they would not meet SET 4.1 and therefore could not be approved.

The Committee is invited:

4. to discuss and make recommendations as to whether the optional status of the standards should be changed.

(The Committee is reminded that the Council is required to consult on any changes to the standards. Any decision to remove the optional part could be further reviewed, in light of responses to the consultation.)

- Supplementary prescribing

The standards of proficiency for physiotherapists, radiographers and chiropodists and podiatrists contain a standard which relates to supplementary prescribing:

- *know and be able to apply the key concepts which are relevant to safe and effective practice practice as a supplementary prescriber in order to have their name annotated on the register* (Standard 2b.4, standards of proficiency, chiropodists and podiatrists, physiotherapists, radiographers).

This standard was added to the standards of proficiency in 2005, to allow the approval of programmes in supplementary prescribing. However, the Council does not publish any further explicit competencies which explain the key concepts or abilities it is necessary to achieve in order to become a supplementary prescriber.

At its meeting on 16th February 2005, the Education and Training Committee agreed that supplementary prescribing programmes should be assessed using Curriculum guidance provided by the document: 'Outline Curriculum for Training Programmes to prepare Allied Health Professional Supplementary Prescribers' (Department of Health

and the National Prescribing Centre, 2004). This outline curriculum includes learning outcomes for supplementary prescribing programmes (attached at appendix 2). [2]

The Executive proposes that it would be helpful for education providers and visitors by providing clarity, if the learning outcomes in this document were more formally adopted by the Committee as the competencies necessary to be a safe and effective prescriber.

The existing supplementary prescribing standard in the standards of proficiency is also somewhat of an anomaly as it appears in pre-registration standards for entry to the Register, but applies to an entitlement which can only be obtained post-registration. The Executive therefore proposes that the standards relating to supplementary prescribing should be removed from the standards of proficiency.

The Committee is invited to agree and recommend to the Council:

5. that the standards relating to supplementary prescribing in the standards of proficiency for physiotherapists, chiropodists and podiatrists and radiographers should be removed; and that

6. the learning outcomes described in the 'Outline Curriculum for Training Programmes to prepare Allied Health Professional Supplementary Prescribers' should be formally adopted as the competencies to be achieved by supplementary prescribing programmes.

Standards of education and training

The Executive has also received feedback from education providers and visitors who have said that a small number of the standards of education and training are not fully applicable to post-registration programmes. The following list gives an indication of some of the possible areas:

- **SET 2: Programme admissions**
  - Some of the requirements of 2.2 ('apply selection and entry criteria') are questionably not relevant when the applicant is already registered.

- **SET 3: Programme management and resource standards**
  - There is no requirement for the Programme leader to have the particular entitlement.

- **SET 4: Curriculum standards**
  - 4.3 (integration of theory and practice) may not be particularly relevant for POM programmes as they have no placements.

- **SET 6: Assessment standards**

[2] http://www.hpc-uk.org/assets/documents/100006C2education_and_training_committee_20050216_enclosure07.pdf.

- 6.7.1/2/3 (assessment regulations must specify requirements…) – Assessment regulations are normally only relevant for university awards and not short courses.

The Health Professions Order 2001 gives the Council the power to establish standards of education and training for additional qualifications which may be marked on the register. Article 19 (6) says that:

"*In respect of additional qualifications which may be recorded on the register the Council may establish standards of education and training and article 15 (3) to (8) and articles 16 to 18 shall apply in respect of those standards as if they were standards established under article 15 (1) (a).*"

These standards could be closely based upon the existing standards of education and training, with additional standards or amended standards as necessary. For example, if the Committee agrees to the previous recommendations about the standards of proficiency, a standard of education and training specific to supplementary prescribing might be that the learning outcomes of the programme must meet the competencies we will publish for supplementary prescribing.

The Committee is invited to agree and recommend to Council:

7. that separate standards of education and training (where necessary) should be produced relating to post-registration programmes leading to entitlements in local anaesthetics, prescription only medicines and supplementary prescribing.

If the Committee is in agreement with points 3 to 7, we would be required to formally consult on the new standards.

Section three: "Approval of programmes leading to entitlements under the Prescription Only Medicines (Human Use) Order 1997" – Professional Liaison Group (PLG)

If the Committee is in agreement with points 1 to 8, the Executive proposes the standards of education and training for LA, POM and SP programmes and competencies for LA and POM should be produced in one document, together with guidance relevant to the approval of these programmes.

This guidance should build upon the standards of education and training guidance (which focuses on pre-registration programmes) to provide specific guidance related to the approval of these programmes. This would include how we propose to approve modules which are part of pre-registration programmes and stand alone programmes.

The Executive proposes that a PLG should be established to draft the document. The PLG should include participation from relevant groups which might include relevant professional bodies, education providers and visitors. The PLG should be chaired by a Council member with registrant and lay council member participation.

The PLG should conclude its work in no more than 3 meetings. A draft plan of activities for the PLG is given at appendix 3.

The Committee is invited to agree and recommend to the Council that: 8. A Professional Liaison Group (PLG) should be established to draft the document.

If the Committee is in agreement, a more detailed workplan with terms of reference will be produced (based on this paper) and submitted to the Council for approval.

Appendix 1: Medicines which can sold, supplied or administered by registered chiropodists and podiatrists with the relevant annotation

Prescription Only Medicines (POM) Sale/ supply	Local Anaesthetics (LA) Administration
○ Co-dydramol 10/500 tablets (amount sufficient for 3 days treatment to max of 24 tablets) ○ Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight ○ Amorolfine hydrochloride lacquer where the maximum strength of the Amorolfine in the lacquer does not exceed 5 per cent by weight in volume ○ Topical hydrocortisone where the maximum strength of the hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight ○ Silver sulfadiazine ○ Amoxicillin ○ Erythromycin ○ Flucloxacillin ○ Tioconazole 28% ○ Potassium permanganate Ointment of heparinoid and hyaluronidase; ○ 9.0% Borotanic complex ○ 10.0% Buclosamide ○ 3.0% Chlorquinaldol ○ 1.0% Clotrimazole ○ 10.0% Crotamiton ○ 5.0% Diamthazole ○ 1.0% Econazole ○ 1.0% Fenticlor ○ 10.0% Glutaraldehyde ○ 0.4% Hydrargaphen ○ Ibuprofen (amount sufficient for 3 days treatment where max dose is 400mg, max daily dose 1,200mg and max pack size is 3,600mg) ○ 2.0% Mepyramine ○ 2.0% Miconazole ○ 2.0% Phenoxyporpan ○ 20.0% Podophyllum ○ 10.0% Polynoxylin ○ 70.0% Pyrogallol	○ Bupivacaine ○ Bupivacaine with adrenaline ○ Lignocaine ○ Lignocaine with Adrenaline ○ Mepivacine ○ Prilocaine ○ Adrelaine (epinephrine) inj BP ○ Methylprednisolone ○ Levobupivacaine Hydrochloride ○ Ropivacaine Hydrochloride

Appendix 1: Medicines which can sold, supplied or administered by registered chiropodists and podiatrists with the relevant annotation

○ 70.0% Salicylic acid ○ 0.1% Thiomersal ○ Terbinafine ○ Griseofulvin 1%	

Outline Curriculum for Training Programmes to prepare Allied Health Professionals as Supplementary Prescribers

This document identifies the key areas a curriculum will need to cover.
Some of the critical issues that Allied Health Professionals will need to address are set out in the introduction and background.

The introduction of supplementary prescribing by chiropodists/podiatrists, physiotherapists and radiographers will be subject to Parliamentary approval to amendments to medicines legislation and NHS regulations, which are not expected before early in 2005

CONTENTS

1 INTRODUCTION AND BACKGROUND

1.1 Background

Supplementary prescribing has its basis in the recommendations of the final report of the Review of Prescribing, Supply and Administration of Medicines, which recommended that two types of prescriber[1] should be recognised:

- "*the independent prescriber who would be responsible for the assessment of patients with undiagnosed conditions and for decisions about the clinical management required, including prescribing."*

- "*the dependent prescriber who would be responsible for the continuing care of patients who have been clinically assessed by an independent prescriber. This continuing care might include prescribing, which would usually be informed by clinical guidelines and be consistent with individual treatment plans, or continuing established treatments by issuing repeat prescriptions, with the authority to adjust the dose or dosage form according to the patients' needs. The Review recommended that there should be provision for regular clinical review by the assessing clinician.* ***(Note: the previous term Dependent Prescriber is now referred to as a Supplementary Prescriber)."***

The *NHS Plan*[2] for England emphasised the need to organise and deliver services around the needs of patients, their families and carers:

"The new approach will shatter the old demarcations which have held back staff and slowed down care. NHS employers will be required to empower appropriately qualified nurses, midwives and therapists to undertake a wider range of clinical tasks including the right to make and receive referrals, admit and discharge patients, order investigations and diagnostic tests, run clinics and prescribe drugs……"

On 4 May 2001, Ministers announced the Government's intention to take steps to introduce supplementary prescribing following the enactment of the Health and Social Care Bill. Ministers subsequently decided that the greatest initial benefit to the NHS and to patients treated within the NHS, would be achieved through the introduction of supplementary prescribing by nurses and pharmacists. Amendments to the Prescription Only Medicines (Human Use) Order 1997 (the POM Order) and NHS Regulations made such a step possible from April 2003. Ministers have now agreed that supplementary prescribing responsibilities should be extended to radiographers, physiotherapists, chiropodists/podiatrists and optometrists, subject to the outcome of Department of Health (DH) and Medicines and Healthcare products Regulatory Agency (MHRA) consultation on supplementary prescribing by these groups[3].

A detailed summary of the policy context and the legal framework can be found in *Supplementary Prescribing A resource to help healthcare professionals to understand the framework and opportunities*[4] published by the National Prescribing Centre (NPC).

1.2 What is supplementary prescribing?

The working definition of supplementary prescribing[1] is:

"….a voluntary partnership between an independent prescriber (a doctor or dentist) and a supplementary prescriber to implement an agreed patient-specific Clinical Management Plan with the patient's agreement".

1.3 Aims of supplementary prescribing

Supplementary prescribing is intended to provide patients with quicker and more efficient access to medicines, and to make the best use of the skills of highly qualified health professionals. It should only be used when there is a clear benefit to both the patient and to the NHS locally (or the independent healthcare provider).

Over time, supplementary prescribing is also likely to reduce doctors' workloads, freeing up their time to concentrate on patients with more complicated conditions, and on more complex treatments.

1.4 Underpinning Principles of the Outline Curriculum

1.4.1 Patient safety is paramount.

1.4.2 The programme will teach participants the general principles of prescribing and how to apply these principles safely within their relevant scope of practice.

1.4.3 The extensive work already carried out by the NPC to develop competency frameworks for prescribing nurses, pharmacists, optometrists and Allied Health Professionals (AHPs) (initially chiropodists/podiatrists, physiotherapists and radiographers), as well as health professionals supplying and administering medicines under Patient Group Directions (PGDs) shows that the core competences needed by these groups are very similar.

1.4.4 This outline curriculum framework currently focuses on supplementary prescribing by Chiropodists/Podiatrists, Physiotherapists and Radiographers - but it is intended that it will be used by other AHPs should prescribing responsibilities be extended to others.

1.4.5 The development of an outline curriculum to prepare AHPs as supplementary prescribers does not mean that all AHPs are necessarily to be trained as supplementary prescribers (Ref: Entry Requirements Paragraphs 2.1 – 2.5)

1.4.6 The development of an outline curriculum to prepare AHPs as supplementary prescribers does not require that AHPs are necessarily to be trained separately from other professions. The decision on how a course will be delivered (i.e. as an AHP only programme or as a wider multiprofessional programme, currently including nurses and/or pharmacists) will be determined locally.

1.4.7 There is normally no automatic entitlement to exemption from any part of the programme although Higher Education Institutions (HEIs) may use established mechanisms for considering exemption from parts of the programme. However students must satisfy all assessment requirements.

1.4.8 The training programme is at post-registration level. The baseline for the programme is judged to be at Level 3 to develop safe supplementary prescribers working within the legal framework. If offered by a Higher Education Institution at Masters Level the course will still need to be able to map to the minima required for Level 3.

1.4.9 For each profession, both the theoretical and the learning in practice components of the training programme will be tailored in content and duration to deliver standards of knowledge and practice against each element of the Curriculum Framework that will allow safe practice.

1.4.10 Programmes will include sufficient emphasis on clinical decision-making, including a decision not to prescribe.

1.5 Current Knowledge Base/Professional Context

The relevant knowledge and expertise of chiropodists/podiatrists, physiotherapists and radiographers entering a training programme will depend on the nature of their practice and the length of their experience. The design and delivery of programmes will need to take account of the programme participants' range of background expertise, experience and skills and will be expected to confirm their competence in prescribing through appropriate assessment strategies.

Since August 2000[5] chiropodists/podiatrists, physiotherapists and radiographers have been able to sell, supply or administer medicines as named individuals under Patient Group Directions.

1.5.1 Chiropodists/Podiatrists

In 1972, exemptions to the Medicines Act (1968) enabled podiatrists to obtain and administer local analgesics (LA) in the course of their professional practice. Approved podiatrists have LA rights identified on their registration certificate issued by the Health Professions Council (HPC).

In addition, podiatrists may now also hold a certificate of competence in the use of other specified medicines, and are able to obtain and supply these to patients in the course of their professional practice. These rights were granted under the Medicines (Pharmacy and General Sale – Exemption) Amendment Order 1998 (1998 Statutory Instrument 107) and the POM Order (1998, Statutory Instruments 108).

Separately certificated courses and examinations leading to both the above are included in all undergraduate podiatry programmes[6]. Postgraduate courses are also available for practitioners to update or gain these qualifications[7,8]. All courses contain elements of general and specific pharmacology and include pharmacokinetics; pharmacodynamics; adverse drug reactions and drug interactions; drug dependency and abuse; and a knowledge of the law. Members of the Society of Chiropodists and Podiatrists in possession of the above certificates, are obliged to undertake periodic continuing professional development in both Local Anaesthesia and Pharmacology for Podiatrists, Access and Supply.

Following the 1998 report on the Supply and Administration of Medicines under Group Protocol, and the subsequent amendments to the Medicines Act 1968, many podiatrists now utilise PGDs to support their clinical work. These are particularly relevant where podiatrists are involved in surgical practice or the conservative management of the high-risk foot.

1.5.2 Physiotherapists

As part of their pre-registration courses[9] all physiotherapists will have:

- significant subjective assessment and interviewing skills and be used to applying these in a range of settings.
- well developed objective assessment and handling skills and have applied these in a range of settings and with a variety of different pathologies.

- good clinical reasoning skills and applied these in a range of settings.
- good decision making skills related to a range of clinical settings.
- an understanding of pathologies of a range of conditions.
- good reflective practice skills both theoretical and applied. Most physiotherapy courses use reflective practice as a learning tool across all levels.

- experience of critically evaluating literature, this skill is developed across all levels but physiotherapists may demonstrate differing levels of ability particularly where they have come from a diploma background.
- a basic knowledge of pharmacology relating to a limited range of medicines. This may relate purely to drug management or it may be more applied to show the interrelationship between drug therapy and physiotherapy intervention.

At a postgraduate level some physiotherapists may:

- have undertaken education in order to use injection therapy to manage, for example, musculoskeletal injuries.
- have experiential knowledge of a range of medicines related to their area of expertise.

1.5.3 Radiographers

Diagnostic Radiographers

As part of their pre-registration courses[10] Diagnostic Radiographers will have a thorough and detailed knowledge and understanding of:

- The pharmacology of medicines commonly encountered within imaging settings with a particular emphasis on contrast agents, associated medicines and pharmaceuticals
- The methods of administration of medicines.

Therapeutic Radiographers

As part of their pre-registration courses[10] Therapeutic Radiographers will have a thorough and detailed knowledge and understanding of:

- The pharmacology of medicines commonly used in the relief of symptoms commonly encountered within the oncology setting, cytotoxic drugs, hormonal agents, imaging contrast agents and radiopharmaceuticals.
- The methods of administration of medicines.

1.6 Professional Codes of Ethics and Standards

1.6.1 Health Professions Council

The regulatory body for AHPs included in this outline curriculum is the HPC. The HPC has produced the following standards, which cover the practice of AHPs.

- Standards of Conduct, Performance and Ethics[11]
- Standards of Education & Training[12]
- Standards of Proficiency – Chiropodists and Podiatrists[13]
- Standards of Proficiency – Physiotherapists[13]
- Standards of Proficiency – Radiographers[13]

1.6.2 It may also be useful to refer programme participants to Codes of Ethics and Professional Conduct issued by professional bodies such as the Society of Chiropodists and Podiatrists[14], Chartered Society of Physiotherapy[15, 16], Society of Radiographers[17].

1.7 Registration and Continuing Professional Development

A joint formal consultation by DH and MHRA on proposals to extend supplementary prescribing to Chiropodists/Podiatrists, Physiotherapists and Radiographers began in May 2004. Subject to the outcome of the consultation it is hoped that supplementary prescribing will be introduced for these professions from early 2005.

1.7.2 It is a legal requirement that, to practise, Allied Health Professionals (who are subject to statutory regulation) must be registered with the Health Professions Council (HPC).

1.7.1 If it is agreed that a Chiropodist/Podiatrist, Physiotherapist or Radiographer can practise as a supplementary prescriber, the registrant must have successfully completed a programme of study approved by the HPC and been issued with appropriate certification.

1.7.4 The Prescription Only Medicines Order made under the Medicines Act will require that the register of the HPC for these registrants be annotated to indicate that the registrant is competent to practise as a supplementary prescriber.

1.7.5 As with all registrants of the HPC, to remain on the annotated register Supplementary Prescribers will have to demonstrate that they continue to meet the Standards of Proficiency for safe and effective practice of their profession. Item 6 of the Council's Standards of Conduct, Performance and Ethics requires that registrants only practise in those fields in which they have appropriate education, training and experience. This involves a self-declaration on renewal of their registration.

1.7.6 From 2005, registrants will also have to meet the requirements of the Standards for Continuing Professional Development (CPD) of the HPC. This will be a self-declaration that they have kept up-to-date with practice within their current context and scope of practice. This will be subject to periodic audit requiring the registrant to submit evidence of their CPD to the HPC for scrutiny to support their claim.

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2 ENTRY REQUIREMENTS

The safety of patients is paramount and the entry requirements focus on protection of patients including:

- The legal requirement to be registered to practise as an allied health professional
- The service need to protect patients – including development of new services and new roles
- Demonstrating and maintaining competence in a clinical speciality
- Supplementary prescribing as an adjunct to high level clinical practice
- Responsibility of services to identify a) where this development needs to occur and b) that potential prescribers are in roles which require such development.

All entrants to the programme must meet the following requirements:

2.1 Be registered with the Health Professions Council in one of the relevant Allied Health Professions

And

2.2 Be professionally practising in an environment where there is an identified need for the individual to regularly use supplementary prescribing

And

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

And

2.4 Have an approved medical practitioner, normally recognised by the employing/Health Service commissioning organisation a) as having experience in a relevant field of practice, b) training and experience in the supervision, support and assessment of trainees, c) who has agreed to;

- Provide the student with opportunities to develop competencies in prescribing
- Supervise, support and assess the student during their clinical placement

And

2.5 Have normally at least 3 years relevant post-qualification experience.

2.6 Programme providers must ensure through pre-programme assessment or from clear documented evidence that candidates have appropriate background knowledge and experience and are able to study at academic level 3.

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3 AIM AND OBJECTIVE OF THE PROGRAMME

3.1 Aim – to develop the knowledge and skills required by an allied health professional to practice as a supplementary prescriber meeting the standards set by the Health Professions Council for entry on the Register as supplementary prescribers.

3.2.1 Objective – AHP supplementary prescribers will be able to demonstrate how they will prescribe safely, effectively and competently.

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4. LEARNING OUTCOMES

By the end of the training programme participants will be able to:

4.1 Demonstrate effective partnership working with Independent Prescriber(s), patient(s) and the wider care team.

4.2 Develop and document a clinical management plan (CMP) within the context of a prescribing partnership.

4.3 Demonstrate effective consultation/assessment [(a)] skills including the following:

4.3.1 Ability to communicate effectively with patients[(b)] and carers.

4.3.2 Ability to conduct a relevant physical assessment/examination of patients with those conditions for which they may prescribe.

4.3.3 The process of effective clinical decision-making.

4.3.4 How to assess patients' needs for medicines, taking account of their wishes, values, ethnicity and the choices they may wish to make in their treatment.

4.4 Understand the way medicines work in relation to the disease process (pharmacodynamics and pharmacokinetics).

4.5 Demonstrate the ability to monitor response to medicines and modify treatment or refer the patient as appropriate.

4.6 Identify sources of information, advice and decision support, eg *Prodigy* in primary care settings, and explain how they will use them in prescribing practice taking into account evidence based practice and national / local guidelines.

4.7 Recognise, evaluate and respond to influences on prescribing practice at individual, local and national levels.

NOTES
(a) Wherever the term consultation is used in the document it refers to consultation/assessment as some professions use the term 'assessment' rather than 'consultation' as overarching terminology meaning the total of communication/physical assessment/decision making.

(b) It is recognised that the terms patient/client/user/customer may be used in different settings. The term patient is used throughout the document and encompasses all these terms.

4.8 Demonstrate an understanding of the legal and professional framework for accountability and responsibility in relation to supplementary prescribing and demonstrate how the law relates to supplementary prescribing practice.

4.9 Demonstrate a reflective approach to continuing professional development of prescribing practice.

4.10 Demonstrate an understanding of the importance of record keeping in the context of medicines management including:

- accurate recording in patients' notes.
- the reporting of near misses.
- adverse reactions.
- ability to access the CMP

♦♦♦♦♦

5 INDICATIVE CONTENT

The following areas of work should all be addressed to meet the learning outcomes for this programme of study.

5.1 Consultation and Decision-Making

5.1.1 When and how to apply the range of models of consultation.

5.1.2 Strategies to develop accurate and effective communication and consultation with professionals, patients and their carers.

5.1.3 How to build and maintain an effective relationship with patients and carers taking into account their values and beliefs.

5.1.4 Partnership working with the patient including the concordant approach and the importance of explaining why medication has been prescribed, side effects and other relevant information to enable patient choice

5.1.5 How to develop and document a CMP including referral to the independent prescriber and other professionals.

5.1.6 How to apply the principles of diagnosis and the concept of a working diagnosis.

5.1.7 How to understand and recognise personal limitations.

5.2 The Psychology of Prescribing and influencing Factors

5.2.1 Strategy for managing patient demand. - Patient demand versus patient need, the partnership in medicine taking, the patient choice agenda and an awareness of cultural and ethnic needs.

5.2.2 The external influences, at individual, local and national levels.

5.2.3 Personal attitudes and their influences on prescribing practice.

5.3 Prescribing in a Team Context

5.3.1 The role and functions of other team members

5.3.2 The professional relationship between independent prescriber (a doctor or dentist) and supplementary prescriber and those responsible for dispensing

5.3.3 The responsibility of the Supplementary Prescriber in the development and the delivery of the CMP.

5.3.4 The importance of communicating prescribing decisions within the team.

5.3.5 Interpretation of documentation including medical records, clinical notes and electronic health records.

5.3.7 How to manage the interface between multiple prescribers, and recognise the potential conflict and how that might be managed.

5.3.8 An overview of prescribing budgets.

5.4 General Principles and Application of Pharmacology and Therapeutics.

5.4.1 Principles of pharmacokinetics[(c)] and drug handling – absorption, distribution, metabolism and excretion of drugs.

5.4.2 Pharmacodynamics[(d)].

5.4.3 Changes in physiology and drug response, for example in the older person, young people, the effect of pregnancy and on women who are breast-feeding and the issues raised by ethnic origin.

5.4.4 Adverse drug reactions, interactions with drugs (including over-the-counter (OTC) products, prescription-only medicines (POMs), Complementary Medicines) and interactions with other diseases

5.4.5 Impact of co-morbidity and other treatments on prescribing and patient management

5.4.6 Selection of drug regimen

NOTES
(c) Pharmacokinetics: the study of the accumulation of drugs within the body, including the routes and mechanisms of absorption and excretion, the rate at which a drug's action begins and the duration of the effect, the biotransformation of the substance in the body, and the effects and routes of excretion of the metabolites of the drug.

(d) Pharmacodynamics: the study of how a drug acts on a living organism, including the pharmacologic response observed relative to the concentration of the drug at an active site in the organism.

5.5 Principles and methods of patient monitoring

5.5.1 Methods for monitoring the patient including interpretation and responding to patient reporting, physical examinations and laboratory investigations.

5.5.2 Relevant physical examination skills.

5.5.3 Assessing responses to treatment against the objectives of the clinical management plan

5.5.4 Working knowledge of any monitoring equipment used within the context of the clinical management plan

5.5.5 Identifying and reporting adverse drug reactions

5.6 Evidence-based Practice and Clinical Governance in relation to Supplementary Prescribing

5.6.1 Principles of evidence-based prescribing

5.6.2 Knowledge of national and local guidelines, protocols, policies, decision support systems and formularies – including rationale for, adherence to and deviation from such guidance

5.6.3 Reflective practice and continuing professional development – role of self and organisation

5.6.4 Auditing, monitoring and evaluating prescribing systems and practice including the use of outcome measures

5.6.5 Risk assessment and risk management

5.6.6 Analysis and learning from medication errors and near misses

5.7 Legal, Policy, Professional and Ethical Aspects

5.7.1 Policy context for prescribing

5.7.2 Professional judgement in the context of HPC Standards of Conduct, Performance and Ethics

5.7.3 Legal Basis for prescribing, supply and administration of medicines

5.7.4 Legal and regulatory aspects of controlled drugs and the practical application of these

5.7.5 Legal implications of advice to self medicate including the use of complementary therapy and OTC medicines

5.7.6 Medicines regulatory framework including Marketing Authorisation, the use of unlicensed medicines and "off-label" use.

5.7.7 Application of the law in practice, professional judgement, liability and indemnity.

5.7.8 Maintenance of professional knowledge and competence in relation to the conditions for which the allied health professional may prescribe.

5.7.9 Individual accountability and responsibility as a supplementary prescriber.

5.7.10 Accountability and responsibility to the employer or commissioning organisation.

5.7.11 Issues relating to consent.

5.7.12 Writing prescriptions in a range of settings.

5.7.13 Prescription pad security and procedures when pads are lost or stolen.

5.7.14 Record keeping, documentation and professional responsibility

5.7.15 Confidentiality, Caldicott and Data Protection

5.7.16 IT developments and their impact on prescribing including electronic patient records, e-prescribing

5.7.16 Suspicion, awareness and reporting of fraud or criminal behaviour, knowledge of reporting and 'whistle blowing' procedures

5.8 Prescribing in the Public Health Context

5.8.1 Duty to patients[(b)] and society

5.8.2 Public health issues and policies, particularly the use of antimicrobials and resistance to them.

5.8.3 Inappropriate prescribing, over and under-prescribing.

5.8.4 Inappropriate use of medicines including misuse, under and over-use

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6. TEACHING, LEARNING AND SUPPORT STRATEGIES

Teaching and learning strategies should be designed to allow students to demonstrate that they are familiar with the clinical conditions for which they may prescribe and their treatment, e.g. through the use of case presentations, seminars, tutorials etc.

They will also demonstrate how theory underpins practice

Teaching and learning strategies should recognise:

6.1 the background knowledge and experience of allied health professionals in aspects of medicines relevant to scope of practice, working with patients and the law relating to practice, recognising that these will vary between individuals/professional groups.

6.2 the requirement for an allied health professional to become familiar with the specified conditions for which they may prescribe and that some individual directed study may be necessary to achieve this.

6.3 the value added to learning by the need for additional self-directed study, group work and multi-disciplinary learning experiences with other trainee supplementary prescribers to ensure they have an appropriate level of knowledge commensurate with their supplementary prescribing responsibilities.

6.4 the value of case studies and significant event analysis in the learning process.

6.5 the need to encourage development of critical thinking skills and reflective practice and the means to accessing appropriate CPD and maintenance of CPD records – such as maintaining a CPD portfolio.

6.6 The period of Learning in Practice should ensure that each AHP can demonstrate:

- competence in the relevant physical examination of patients with those conditions for which they may prescribe
- ability to monitor and assess the responses of patients to treatment against the objectives in the clinical management plan and ability to make relevant changes to medication within the parameters detailed within the CMP
- appropriate clinical decision-making
- effective communication with the patient, the Independent Prescriber and the wider care team

- appropriate record-keeping
- ability to document their learning as a Supplementary Prescriber.

6.7 The sponsoring organisation e.g. a primary care organisation or NHS Trust, and the education provider must ensure that the designated registered medical practitioner who provides supervision, support and shadowing opportunities for the student is familiar with the requirements of the programme and the need to achieve the learning outcomes.

6.8 The education provider must support the designated registered medical practitioner with a suitable framework (competence framework) to assess Learning in Practice

6.9 The role of the designated registered medical practitioner in assessing/verifying the clinical learning outcomes relating to the period of Learning in Practice.

6.10 The requirements for supervised learning in practice for nurses and midwives are detailed on the DH website and may be helpful to those developing programmes to train AHPs as supplementary prescribers.[15]

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7. ASSESSMENT STRATEGIES

7.1 The assessment requirements must be made explicit, in particular the criteria for pass/fail and the details of the marking scheme.

7.2 Assessment strategy should ensure that all the learning outcomes for the supplementary prescribing programme are able to be tested, both theory and practice

7.3 The learning outcomes should be assessed by a combination of methods to test knowledge, skills and a reflective approach to learning

7.4 Completion of the programme and confirmation of an award must be conditional on satisfactory completion of the practice experience. Poor performance in this element must not be compensated by other elements of the assessment.

7.5 Assessment strategies must be designed to confirm that the AHP is a safe and effective supplementary prescriber and that a major failure to identify a serious problem or an answer that would cause a patient harm should result in overall failure.

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8. LENGTH OF PROGRAMME

8.1 The duration of the theoretical programme is expected to be at least **26 days**, normally over a period of three to six months and no longer than a period of twelve months. The programme will be expected to contain a range of delivery methods. In finalising programme requirements for this curriculum, the following factors will be taken into account:

8.1.1 The views of education providers on a realistic programme to deliver the curriculum normally over a period of three to six months to achieve the learning outcomes

8.1.2 The compatibility of programmes for allied health professionals and supplementary prescribers from other disciplines provides opportunity to consider shared learning experiences

8.1.3 The programmes for allied health professionals should contain an element of additional directed private study on the defined conditions and medicines for which they will be expected to prescribe treatments.

8.2 The period of learning in practice for an individual allied health professional should be sufficiently long to enable the allied health professional to demonstrate competence in the skills of supplementary prescribing practice and should be a minimum of **12 days**.

8.3 The length of the programme is expected to be at least **26 days** for the theoretical component and at least **12 days** for the learning-in-practice programme – a total of at least **38 days**.

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ANNEX 1

A. Membership of Allied Health Professional Supplementary Prescribing Steering Group

Ruth Allarton	Sheffield Hallam University
Dr Sati Ariyanayagam	GMC representative
David Ashcroft	Society of Chiropodists and Podiatrists
Dr Peter Clappison	Department of Health
Lesley Coles	University of Southampton
Mike Cummins	Department of Health
Dr Catherine Duggan	Academic Department of Pharmacy, Barts and the London NHS Trust
Kay East (Chairperson)	Department of Health
Christina Freeman	Society and College of Radiographers
Trudy Granby	National Prescribing Centre
Clive Jackson	National Prescribing Centre
Julie Kinley	Nurse Supplementary Prescriber
Professor Mary Lovegrove	London South Bank University
Karen Middleton	Department of Health
Robin Miles	Department of Health
Maureen Morgan	Department of Health
Shelagh Morris	Department of Health
Dr John Mucklow	Keele University
Jim Pickard	University of Huddersfield
Paul Robinson	Department of Health
Pen Robinson	Chartered Society of Physiotherapy
Gul Root	Department of Health
Pat Saunders	Department of Health
Marc Seale	Health Professions Council
Anne Thyer	Medicines & Healthcare Products Regulatory Agency
Dr Peter Wilson	Royal Pharmaceutical Society of Great Britain

B. Membership of Draft Outline Curriculum Framework Planning group

Ruth Allarton	Sheffield Hallam University
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Trudy Granby	National Prescribing Centre
Professor Mary Lovegrove	London South Bank University
Carole Marsden	Department of Health
Robin Miles	Department of Health
Shelagh Morris (Chairperson)	Department of Health
Dr John Mucklow	Keele University
Jim Pickard	University of Huddersfield
Gul Root	Department of Health
Pat Saunders	Department of Health
Rebecca Taylor	Department of Health
Eileen Thornton	Health Professions Council
Dr Peter Wilson	Royal Pharmaceutical Society of Great Britain
Lorraine Wright	Trent Workforce Development Confederation

Appendix 3

Draft plan of activities

March 2007

Education and Training Committee meeting, 28th March 2007 - Recommendation to Council

May 2007

Council meeting, 31st May 2007 – Council approval

August 2007

First meeting of the PLG in early August

September 2007

Second meeting of the PLG in late September

November 2007

Third and final meeting of the PLG in early November

December 2007

Education and Training Committee, 4th December 2007 – Recommend finished document to Council

Council meeting, 13th December 2007 - Council approval

February to April 2008

Consultation

May 2008

Education and Training Committee meeting – consider final document and consultation responses

July 2008

Council meeting, 3rd July 2008 – approval of document for publication