

**Health Professions Council
Council, 31st May 2007**

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

Executive Summary and Recommendations

Introduction

At its meeting on 29th March 2007, the Education and Training Committee considered a paper from the Executive about the Approval of programmes leading to entitlements under the Prescription Only Medicines (Human Use) Order 1997. The Committee made three recommendations to Council.

The attached paper is redacted from the paper considered by the Education and Training Committee at its last meeting. The Committee is due to consider a further paper at its meeting on 12th June 2007, regarding other issues around the approval of programmes leading to local anaesthetic, prescription only medicines and supplementary prescribing entitlements. A further paper may therefore be brought to the Council at a subsequent meeting.

Decision

The Council is invited to agree the Education and Training Committee's recommendations that:

1. 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 at present).

The Council is further invited to agree the Education and Training Committee's recommendation that a consultation should be held on whether the standards of proficiency for chiropodists and podiatrists which relate to LA and POM should remain optional.

The Education and Training Committee will be asked to approve a consultation letter at their meeting in September 2007.

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 and podiatrists who have their names annotated on the register.

Date of paper

1st May 2007

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

Section 1: Background and context

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 an 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.

Section 2: Approval of programmes leading to the prescription only medicines (POM) and Local Anaesthetic (LA) entitlements

Current approval arrangements

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 Register¹).

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.

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.

Recommendations

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.

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.

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.

If agreed, the change would be effective from the date of the Council's decision. 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.

On 29th March 2007, the Education and Training Committee agreed with these recommendations and recommended approval by the Council.

Section 3: Standards of proficiency: Local Anaesthetics and Prescription Only Medicines

Standards of Education and Training

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).*

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 but 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 are 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.

At its meeting on 29th March 2007, the Education and Training Committee discussed these issues, and recommended that the Council should consult on proposals that these standards should no longer be optional.

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
<ul style="list-style-type: none"> ○ 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 	<ul style="list-style-type: none"> ○ 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

<ul style="list-style-type: none">○ 70.0% Salicylic acid○ 0.1% Thiomersal○ Terbinafine○ Griseofulvin 1%	
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