

Agenda Item 14(iv)

Enclosure 14

**Health and Care Professions Council
21 September 2016**

**Annotation of medicine exemptions for
orthoptists**

For discussion and approval

From Hollie Latham, Policy Officer

Council, 21 September 2016

Annotation of medicine exemptions for orthoptists

Executive summary and recommendations

Introduction

Legislative amendments which came into effect on 1 April 2016 introduced exemptions to enable orthoptists to sell and supply certain prescription only medicines on their own initiative. A further amendment is needed in order to require orthoptists to obtain an annotation on the HCPC Register before using the exemptions in their practice. This is now not expected to be in place until April 2017.

This paper provides background information on the work undertaken so far in this area; and presents options and the Executive's recommendation for progressing work leading to the annotation of medicine exemptions for orthoptists. This approach was agreed by the Education and Training Committee at their meeting in September 2016.

Decision

The Council is invited to discuss and agree to continue work aimed at annotation of medicine exemptions for orthoptists, including publishing standards and progressing the education approval process.

Background information

- Education and Training Committee, 9 June 2016. Outcomes of the consultation on draft standards for the use of exemptions by orthoptists to sell, supply and administer medicines.
<http://www.hcpc-uk.org/assets/documents/1000504FEnc06-Outcomesoftheconsultationondraftstandardsfortheuseofexemptionsbyorthoptiststosell,supplyandadministermedicines.pdf>
- Education and Training Committee, 4 June 2015. Consultation on draft standards for the use of exemptions by orthoptists to sell, supply and administer medicines.
<http://www.hcpc-uk.org/assets/documents/10004BCFEnc07-Consultationonstandardsfortheuseofexemptionsbyorthoptiststosellsupplyandadministermedicines.pdf>
- Education and Training Committee, 5 March 2015. Extension of prescribing rights and use of exemptions from medicines legislation.

<http://www.hcpc-uk.org/assets/documents/10004AC5Enc07-Extensionofprescribingrightsanduseofexemptionsfrommedicineslegislation.pdf>

Resource implications

None as a result of this paper. A major project is already in progress to enable annotation of orthoptists' entries in the registration system and online Register.

Financial implications

None as a result of this paper. A major project is already in progress to enable annotation of orthoptists' entries in the registration system and online Register.

Appendices

None

Date of paper

9 September 2016

Annotation of medicine exemptions for orthoptists

1. Introduction

- 1.1 This paper provides background on the work being undertaken to introduce medicine exemptions for orthoptists; and presents a recommendation for how to progress with the annotation of the Register for this new entitlement.
- 1.2 Due to an error, there has been a delay in making the necessary changes to legislation to require orthoptists to gain an annotation on the Register before using the exemptions in their practice. The amendment is now expected to be in place in April 2017, although further delays are possible.
- 1.3 The Council is invited to agree that it should:
 - publish the standards for the use of exemptions by orthoptists and begin the process of approving programmes against those standards; and
 - exercise its discretionary powers to annotate the Register entries of orthoptists who successfully complete approved training in the use of medicine exemptions (should the necessary legislation which would mandate this not be in place at that time).

2. About annotation of the Register

- 2.1 The Council has discretionary powers to annotate the Register to indicate where a registrant has undertaken additional training, as set out in the Health and Social Work Professions Order 2001 and in the Health and Care Professions Council (Parts and Entries in the Register) Order of Council 2003¹. Annotating the Register enables us to set standards for a particular area of practice and approve the programmes delivering training in that area.
- 2.2 The Council may also be required by legislation to annotate the Register for certain entitlements – for example, we are required to annotate supplementary and independent prescribers on the Register.
- 2.3 A policy statement on annotation of the Register was agreed in 2012², which states that in most cases the Council would only annotate where legally required to do so or in exceptional circumstances where there is evidence of a risk to public protection in a specific area which can be mitigated through annotation and not through other processes.

¹ See <http://www.hcpc-uk.org/aboutus/legislation/>

² The policy statement is available here: <http://www.hcpc-uk.org/assets/documents/10003DFAPolicystatementonannotationoftheRegisterfinalHCPC.pdf>

3. Work undertaken so far

AHP Medicines Project

- 3.1 Since 2014, NHS England, alongside the Medicines and Healthcare Products Regulatory Agency (MHRA) and the departments of health in the four countries, has been leading work to introduce exemptions in legislation to enable appropriately trained orthoptists to sell and supply certain prescription only medicines on their own initiative. The HCPC is represented on the AHP Medicines Project Board which oversees this work.
- 3.2 The proposal was that, in order to gain the entitlement, orthoptists would need to complete an HCPC approved training programme and be annotated on the HCPC Register. In collaboration with the British and Irish Orthoptic Society (BIOS) and with input from other members of the AHP Medicines Project Board, a case of need was developed, along with draft practice guidance and an outline curriculum framework for the forthcoming training.
- 3.3 NHS England ran a consultation on the proposal between February and April 2015. The outcomes of the consultation were then presented for consideration by the Commission on Human Medicines (CHM), which is responsible for advising government ministers on medicines issues, in September 2015. The CHM subsequently recommended in favour of introducing the exemptions, and the responsible minister made a statement supporting the necessary legislative amendments in February 2016.
- 3.4 The medicines included in the proposed exemptions are all administered topically (as eye drops or ointments) and are already used by many orthoptists in their day-to-day practice. Orthoptists are currently able to supply or administer these medicines via other mechanisms, such as Patient Group Directions (PGDs) or patient specific directions.

HCPC standards

- 3.5 Alongside these developments, the Executive produced a new set of standards to facilitate annotation of the Register. The standards include requirements for education providers delivering training to orthoptists in the use of the exemptions; as well as the threshold level of knowledge, understanding and skills that orthoptists would need to be able to use the exemptions safely and effectively.
- 3.6 We held a public consultation on the draft standards between March and May 2016. Responses to the consultation indicated overwhelming support for the standards among stakeholders, and the standards were agreed by the Council in July 2016.
- 3.7 We anticipated publishing the standards in October 2016. We would normally wait until necessary legislation is in place before publishing standards.

Approval of training programmes

- 3.8 As mentioned above, the introduction of medicine exemptions for orthoptists requires new post-registration training programmes to be developed by education providers. These would need to undergo the normal education approval process, assessed against the forthcoming standards.
- 3.9 Once the standards have been published, providers would be able to request an approval visit. The whole approval process normally takes about nine months.
- 3.10 Based on discussions with BIOS, we are aware that up to three education providers are considering developing new training programmes for orthoptists in the use of exemptions. Programmes are expected to last about 12 weeks, comprising an online or residential theory part, as well as work-based practice learning.

Cross-departmental project

- 3.11 A cross-departmental project has been underway since April 2016 to make changes to the registration system and online register in order to display additional annotations³. The changes are expected to go live in mid-September.

4. Amendments to legislation

- 4.1 In late February 2016, changes to the Human Medicines Regulations 2012 ('the 2012 regulations') were introduced via the Human Medicines (Amendment) Regulations 2016, which came into effect on 1 April.⁴
- 4.2 This amended Schedule 17, Part 1, of the 2012 regulations (exemptions from restrictions on sale and supply of prescription only medicines) to include a reference to 'registered orthoptists' and a list of nine prescription only medicines to be included in the exemption. However, it fails to specify that orthoptists must have annotations against their names in the Register to signify that they are qualified to use the medicines.
- 4.3 We immediately brought this error to the attention of the MHRA, the agency responsible for drafting medicines legislation, who proposed that a second amendment could be made in October 2016 to correct this and add the reference to annotation.
- 4.4 However, in August 2016 we were informed that the amendment would likely be made in April 2017 instead, as there are no other amendments to the 2012 regulations needed at this time.

³ The project also includes implementing the annotations for supplementary prescribing for dietitians and independent prescribing for therapeutic radiographers.

⁴ Human Medicines Regulations 2012: <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>
Human Medicines (Amendment) Regulations 2016:
http://www.legislation.gov.uk/uksi/2016/186/pdfs/uksi_20160186_en.pdf

- 4.5 Therefore, at the time of writing there is no legal requirement for an orthoptist to gain an annotation on the Register before using the medicine exemptions in their practice. Without annotation, there would also be no obligation for us to publish standards or to approve training programmes against them.

5. Executive recommendation

- 5.1 We recommend that the Council should exercise its powers to annotate the Register entries of orthoptists who are qualified to use medicine exemptions, even in the absence of legislation which requires annotation. If agreed, the requirement for orthoptists to undertake post-registration training and gain an annotation would be set as a regulatory expectation, rather than a legal obligation.
- 5.2 This would mean that work to implement the annotation would proceed as originally planned, including publishing the standards in October 2016 and enabling education providers to request approval visits to new programmes from that point. The first programmes could then commence from around July 2017.
- 5.3 It is expected that by the time the training programmes commence, the necessary legislative amendment will already be in place. However, if this is not the case because of a further delay, we recommend that annotation of the Register should be implemented anyway in the interest of public protection.
- 5.4 We have received advice from the Solicitor to the Council that for public protection reasons, orthoptists should be expected to gain an annotation through completion of an approved programme before exercising the new entitlement. Whilst we do not have evidence of a serious risk to the public, there will certainly be some risk involved in this extension of an orthoptist's practice. The skills and knowledge needed to sell and supply the medicines without a prescription are not included in the standards of proficiency for entry to the profession.
- 5.5 The alternative – i.e. waiting until the necessary legislative amendment is in place before publishing the new standards or progressing the education approval process – would represent a delay of at least six months for orthoptists to be able to train to use the medicine exemptions in their practice. Assuming that the amendment is in place in April 2017, education providers would be able to request approval visits at that time, with the first programmes commencing from around January 2018 (following a nine-month process).
- 5.6 We have supported the AHP Medicines Project, and the introduction of medicine exemptions for orthoptists in particular, because of the benefits that use of the exemptions will bring to patients in terms of timely access to medicines. The project has already been delayed due to the timing of legislation and other issues throughout its duration; we would be in favour of avoiding a further delay if possible.

- 5.7 In addition, further delay in publishing the standards and approving programmes may result in confusion among orthoptists about whether they are able to sell or supply the medicines in their practice; or to inconsistency in the training programmes which are being developed.
- 5.8 On the other hand, publishing the standards and assessing new programmes against them as planned would allow the Council to have assurance of the quality and effectiveness of the new training programmes, whilst still expecting that the necessary legislation will be in place before the first orthoptists begin their training, or soon after.