
Consultation on draft standards for the use of exemptions by orthoptists to sell, supply and administer medicines

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1. Introduction

About this consultation

- 1.1 We are the Health and Care Professions Council (HCPC). This consultation seeks the views of stakeholders on our draft standards for the use by orthoptists of exemptions within medicines legislation.
- 1.2 We have developed these standards alongside the introduction of legislative exemptions for orthoptists to be able to sell, supply and administer certain medicines throughout the United Kingdom without the need for a prescription. This proposal has been led by NHS England, in conjunction with the devolved administrations.
- 1.3 We are consulting on the understanding that in future we will annotate the HCPC Register entries of orthoptists who are qualified to use the exemptions and will approve programmes delivering relevant training. The development of standards allows us to set out what is necessary for safe and effective practice by orthoptists who sell, supply or administer medicines via exemptions.
- 1.4 This document explains the background to development of the standards and sets out the draft standards for consultation.
- 1.5 This consultation will be of particular interest to registered orthoptists; other health professionals working alongside orthoptists as part of the multidisciplinary team; service providers; professional bodies; education providers; and those who use orthoptist services and their carers.
- 1.6 This consultation will run from **8 March to 3 May 2016**.

About this document

- 1.7 This document is divided into six sections.
 - **Section one** introduces the document.
 - **Section two** provides background information about exemptions and the changes to legislation.
 - **Section three** describes the existing system of regulation with regard to the use of exemptions.
 - **Section four** explains our approach in drafting the new standards for orthoptists and how we will use them in the future.
 - **Section five** provides information on proposed implementation of the standards and future work.
 - **Section six** sets out the draft standards for consultation.

About us

- 1.8 We are a regulator and were set up to protect the public. To do this, we keep a Register of professionals who meet our standards for their professional skills and behaviour. Individuals on our Register are called 'registrants'.
- 1.9 We currently regulate 16 professions.
- Arts therapists
 - Biomedical scientists
 - Chiropodists / podiatrists
 - Clinical scientists
 - Dietitians
 - Hearing aid dispensers
 - Occupational therapists
 - Operating department practitioners
 - Orthoptists
 - Paramedics
 - Physiotherapists
 - Practitioner psychologists
 - Prosthetists / orthotists
 - Radiographers
 - Social workers in England
 - Speech and language therapists

Consultation questions

1.10 We would welcome your response to this consultation. We have listed some consultation questions below to help you. These questions are not exhaustive and we would also welcome your comments on any related issue. Please provide reasons alongside your answers where possible.

- Q1. Do you think the standards are set at the level necessary for safe and effective sale, supply and administration of medicines via exemptions?
- Q2. Do you think the standards relating to practice placements (D1-D11) are appropriate?
- Q3. Do you think any additional standards are necessary?
- Q4. Do you think there are any standards which should be reworded or removed?
- Q5. Do you have any comments about the language used in the standards?

Q6. Do you have any other comments on the standards?

How to respond to the consultation

1.11 You can respond to this consultation in one of the following ways:

- By completing our easy-to-use online survey:
<https://www.research.net/r/standardsorthoptistexemp>
- By emailing us at: consultation@hcpc-uk.org
- By writing to us at:

Consultation on standards for the use of exemptions by orthoptists
Policy and Standards Department
The Health and Care Professions Council
Park House
184 Kennington Park Road
London
SE11 4BU

Fax: +44(0)20 7820 9684

1.12 Please note that we do not normally accept responses by telephone or in person. We ask that consultation responses are made in writing to ensure that we can accurately record what the respondent would like to say. However, if you are unable to respond in writing please contact us on +44 (0)20 7840 9815 to discuss any reasonable adjustments which would help you to respond.

1.13 **Please contact us to request a copy of this document in an alternative format, or in Welsh.**

1.14 Once the consultation period has finished, we will analyse the responses we have received. We will then publish a document detailing the comments received and explaining the decisions we have taken as a result. This will be available on our website. If you would prefer we do not make your response public, please indicate this when you respond.

1.15 We look forward to receiving your comments.

2. Background

Supply and administration of medicines by orthoptists

- 2.1 The ability of health professionals to supply and administer prescription-only medicines to patients is governed by the Medicines Act 1968 and related regulations, including the Human Medicines Regulations 2012 which consolidate many previous enactments¹.
- 2.2 Orthoptists are not able to prescribe medicines for patients in the way that doctors, dentists and some other health professionals can. However they may supply or administer medicines without a prescription in one of two ways:
- Patient specific direction (PSD): where an independent prescriber gives an instruction to another professional to administer a medicine to a specific patient;
 - Patient group direction (PGD): where a written instruction is agreed and signed by a doctor and pharmacist for the supply or administration of specific medicines by named health professionals to certain groups of patients (for example with the same treatment needs).
- 2.3 These current mechanisms work well where a patient falls within predictable criteria, or where the orthoptist works in a multidisciplinary team with easy access to a doctor or other independent prescriber. However they have limitations in other circumstances – for example where a patient has unpredicted treatment needs, or the orthoptist does not work alongside an independent prescriber.

About exemptions in medicines legislation

- 2.4 Exemptions allow some health professional groups to sell, supply and/or administer certain listed medicines to patients without the need for a prescription or another supply or administration mechanism (such as a PSD or PGD).
- 2.5 Currently, HCPC-registered paramedics and chiropodists / podiatrists can use exemptions in their practice. All registered paramedics are able to administer certain prescription-only medicines on their own initiative in emergency situations.² Chiropodists / podiatrists who have undertaken relevant training can use exemptions to administer from a discrete list of medicines including a range of local anaesthetics; and to sell or supply other prescription-only medicines.
- 2.6 The use of exemptions to sell, supply or administer prescription-only medicines is not the same thing as prescribing.

¹ Medicines Act 1968 <http://www.legislation.gov.uk/ukpga/1968/67>
Human Medicines Regulations 2012 <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>

² This exemption is not annotated on the HCPC Register as it applies to all registered paramedics.

Recent legislative changes

- 2.7 NHS England ran a public consultation between February and April 2015 on proposals to introduce exemptions enabling orthoptists to sell, supply and administer certain prescription-only medicines on their own initiative, within the scope of their practice and without the usual need for a prescription³.
- 2.8 The proposals were presented for consideration by the Commission on Human Medicines (CHM) in September 2015. The CHM subsequently made a recommendation to the responsible government ministers supporting the introduction of exemptions for orthoptists.
- 2.9 The exemptions will cover nine medicines, including antibiotics and other medicines which many orthoptists already use as part of their normal practice through other mechanisms (PSDs and PGDs). It is anticipated that the ability to use exemptions would enable orthoptists to sell, supply or administer medicines within their competence in the absence of a PGD and where a doctor or other independent prescriber is not readily available.
- 2.10 The exemptions will apply throughout the United Kingdom, and will be lawful in any setting in which orthoptists work.
- 2.11 In order to use the exemptions, an orthoptist will need to be registered with the HCPC and to have completed an approved post-registration training course. Education providers have indicated that this training is likely to comprise a theory component as well as a practice-based component within the orthoptist's own workplace. Training on the use of exemptions to sell, supply and administer medicines is not currently a part of pre-registration (undergraduate) orthoptist education and training.
- 2.12 The Human Medicines (Amendment) Regulations 2016, which introduce the list of medicines included in the exemptions, were made in late February 2016. We are proceeding with this consultation on the understanding that further legislation will be introduced later this year which will require orthoptists to have an 'annotation' or mark on the HCPC Register before being eligible to use the exemptions. That legislation is expected to come into effect in October 2016⁴.

³ A summary of the consultation responses can be found at <https://www.england.nhs.uk/wp-content/uploads/2016/02/orthoptists-summary-consult-responses.pdf>

⁴ We understand that the government intends to introduce a further amendment to the Human Medicines Regulations 2012 later this year. Once this amendment is in place, there will be a requirement for orthoptists to undertake additional post-registration training and to gain an annotation before using the legislative exemptions to sell, supply or administer the listed medicines.

3. Regulation of the use of exemptions

Setting standards

- 3.1 We set standards to ensure safe and effective practice by our registrants. The existing standards of proficiency for orthoptists⁵ do not contain standards relating to the sale, supply or administration of medicines to patients through exemptions. As orthoptists will undertake post-registration training in order to be able to use exemptions, we have produced a separate set of standards. This is a similar approach to the standards for prescribing, which we use in approving post-registration programmes that allow registrants in some professions to train as independent or supplementary prescribers.⁶
- 3.2 Once approved, the new standards would apply to programmes delivering training in the use of exemptions, as well as to orthoptists who are qualified to use exemptions in their practice.

Approval of education and training programmes

- 3.3 The HCPC has a role in approving and monitoring training programmes which enable professionals to qualify to use exemptions. The purpose of this process is to ensure that upon completion of a programme, a professional is able to sell, supply and administer medicines to patients on their own initiative safely and effectively.
- 3.4 The use of exemptions for the sale, supply and administration of medicines is not currently included in pre-registration education and training for orthoptists, so new post-registration programmes would need to be developed by education providers.
- 3.5 We would use the new standards we have developed when making decisions about approval of relevant training programmes for orthoptists on the use of exemptions, as well as in subsequent monitoring of these programmes. It would be up to education providers to decide how to design a programme so that upon completion, orthoptists are able to meet the new standards and to sell, supply and administer medicines using exemptions safely and effectively.

Annotation of the Register

- 3.6 We currently annotate (or mark) the Register where chiropodists / podiatrists are qualified to use exemptions to administer certain medicines including local anaesthetics; and to sell or supply certain other medicines. These annotations are called 'local anaesthetics' (LA) and 'prescription only medicines' (POM), respectively. A professional cannot use these exemptions in their practice

⁵ The standards of proficiency for orthoptists, which set out the threshold level of knowledge, skills and understanding for entry to the profession can be found on the HCPC website: <http://www.hcpc-uk.org/publications/standards/index.asp?id=47>

⁶ The HCPC standards of prescribing can be found on our website: <http://www.hcpc-uk.org/aboutregistration/standards/standardsforprescribing/>

unless they have completed appropriate training and had their entry on the Register annotated.

- 3.7 Once the further legislative amendments come into force, we will be required to annotate the Register to indicate those orthoptists who may use the exemptions. The annotation will ensure that only appropriately trained orthoptists can use the exemptions and also will enable service users and members of the public to see who is qualified.

4. The proposed standards

- 4.1 We have developed a new set of standards for the use of exemptions by orthoptists to sell, supply and administer medicines. These are set out in section six.
- 4.2 The proposed standards are divided into two parts:
- The first part contains standards for education providers delivering training for orthoptists in using exemptions to sell, supply and administer medicines. This part sets out the systems and processes that we expect an education provider to have in place in order to ensure that a student is capable of using exemptions safely and effectively upon completion of the programme.
 - The second part sets out the skills, knowledge and understanding that orthoptists will need to demonstrate in order to use exemptions safely and effectively in their practice.
- 4.3 The standards have been set at what we consider to be the threshold level for safe and effective practice.

Drafting the standards

- 4.4 In drafting the standards we looked at the following:
- our standards of education and training (SETs), which set out requirements for education providers delivering pre-registration training across all HCPC-regulated professions⁷;
 - our standards of proficiency for orthoptists, which set out the knowledge, skills and understanding expected of orthoptists at entry to the Register;
 - our standards for prescribing; and
 - the learning outcomes contained in the draft outline curriculum framework developed by the British and Irish Orthoptic Society (BIOS) for education providers who will deliver training for orthoptists in using exemptions⁸.
- 4.5 In addition, we have sought feedback from BIOS and from education providers who intend to develop new training programmes for orthoptists on the use of exemptions. Conversations with these stakeholders have been useful in ensuring that the proposed standards are appropriate and realistic, given the likely format of training programmes and envisaged use of exemptions by orthoptists in the future.
- 4.6 When drafting the standards we were mindful of the fact that orthoptists who are qualified to use exemptions would continue to be required to meet all of the other standards set by the HCPC. This includes the standards of

⁷ The SETs and accompany guidance can be found on our website: <http://www.hcpc-uk.org/aboutregistration/standards/sets/>

⁸ The 'Outline Curriculum Framework for Education Programmes to prepare Orthoptists to use exemptions' can be found on the BIOS website: <https://orthoptics.org.uk/Exemptions-&-Consultation>

proficiency for orthoptists; the standards of conduct, performance and ethics; and the standards for continuing professional development⁹.

- 4.7 Therefore, the proposed standards do not duplicate aspects of other existing HCPC standards which orthoptists must already adhere to as a condition of their registration. This includes requirements in relation to competencies they would have gained through their pre-registration education and training; as well as standards about their conduct, health and continuing professional development. The proposed standards are narrowly focused on those aspects which are necessary for the safe and effective use of medicines via exemptions, above and beyond the requirements we set for all orthoptists.

Practice placements

- 4.8 The proposed standards include a section in the first part for education providers on practice placements (standards D1 to D11).
- 4.9 Discussions with education providers during development of the standards indicated that the practice-based component of the forthcoming training programmes would most likely be undertaken within the orthoptist's own workplace. During this part of the training, the orthoptist would likely be expected to complete a reflective diary or logbook alongside their normal work, in order to demonstrate their knowledge and understanding about how they would make decisions and sell, supply or administer medicines using exemptions in their practice once qualified to do so.
- 4.10 The proposed standards require the education provider to maintain oversight of the practice-based component, including approval and monitoring of the quality, appropriateness and safety of practice placements.
- 4.11 We recognise that education providers' envisaged format for the practice-based component of the programme does not fall under what might normally be described as a 'practice placement' – i.e. the type of clinical or practical placement which is required for pre-registration education and training in all of our regulated professions. However, it is important for the practical element of the training to be reflected in these standards. An orthoptist at entry to the Register may not necessarily have obtained the requisite skills, for example in decision making and administration of certain medicines (though we recognise that many will have).
- 4.12 We have retained the term 'practice placement' for consistency with the other standards we set for education providers, including our standards for prescribing.
- 4.13 It is not the intention to require a designated medical practitioner (DMP) or other appointed supervisor to oversee the practice-based part of the training (as is the case for training in independent and supplementary prescribing). We understand from discussion with BIOS and education providers that the

⁹ All HCPC standards are available here: <http://www.hcpc-uk.org/aboutregistration/standards/>

practice-based component of training would likely be carried out without additional supervision on top of what the orthoptists would have in their normal working roles. The reflective diary or logbook would be submitted to the education provider for assessment, rather than being assessed by a supervisor at the practice placement.

- 4.14 However, in keeping with our approach to other post-registration qualifications, such as for supplementary and independent prescribing, POM and LA programmes, we have proposed standards which require an appropriate person at the practice placement to assume responsibility for the orthoptist's participation in this component. The individual in this role (the 'practice placement educator') would not necessarily have to play a part in any formal assessment of skills but should communicate and collaborate with the education provider where necessary.
- 4.15 We will be particularly interested to hear what respondents to this consultation think about the appropriateness and proportionality of the proposed standards relating to practice placements, and whether they are set at the level necessary for safe and effective use of exemptions by orthoptists.

How we will use the standards

- 4.16 We will use these standards when we approve and subsequently monitor programmes delivering training for orthoptists in using exemptions. We will visit the programmes to assess them against the standards, as part of our rigorous approval process. A programme which does not meet one or more of the standards would have conditions attached to its approval; and if these conditions were not met, this would lead to approval being refused. Approved programmes would be monitored on an on-going basis against the standards. A programme which did not continue to meet them would have their on-going approval withdrawn.
- 4.17 As the second part of the standards sets out the knowledge, understanding and skills required for orthoptists to be able to use exemptions safely and effectively, we will take into account these standards (as well as our other standards) in the future when we consider concerns raised about the competence of an orthoptist who sells, supplies or administers medicines to patients using exemptions.

5. Implementation

- 5.1 This consultation closes on **3 May 2016**. After that time we will analyse all of the responses received and publish our response to any issues raised.
- 5.2 We anticipate publishing the standards in the autumn of 2016. The new training programmes for orthoptists will then be able to commence from around mid-2017.

Future work

- 5.3 Following the expected publication of the standards for use of exemptions by orthoptists, we will consider future work to develop a generic (i.e. cross-professional) set of standards for the use of exemptions. This would include the use of exemptions by chiropodists / podiatrists referred to in section two, as well as by orthoptists. It would also afford an opportunity to ensure that the standards would continue to be applicable in case of future introduction of exemptions for other HCPC-registered professions.
- 5.4 We would consult on these generic standards for use of exemptions and, if approved, they would supersede the standards for orthoptists only, which are the subject of this present consultation.

6. Draft standards for consultation

- 6.1 The draft standards for the use of exemptions by orthoptists to sell, supply and administer medicines are set out below.

Standards for the use of exemptions by orthoptists to sell, supply and administer medicines

Standards for education providers

Admissions	
A.1	The admissions procedures must give both the applicant and the education provider the information they require to make an informed choice about whether to take up or make an offer of a place on a programme.
A.2	The admissions procedures must apply selection and entry criteria, including appropriate academic and professional entry standards.
A.3	The admissions procedures must apply selection and entry criteria, including accreditation of prior (experiential) learning and other inclusion mechanisms.
A.4	The admissions procedures must ensure that the education provider has equality and diversity policies in relation to applicants and students ¹⁰ , together with an indication of how these will be implemented and monitored.

Programme management and resources	
B.1	The programme must have a secure place in the education provider's business plan.
B.2	The programme must be effectively managed.
B.3	The programme must have regular monitoring and evaluation systems in place.
B.4	There must be a named person who has overall professional responsibility for the programme who must be appropriately qualified and experienced and, unless other arrangements are agreed, be on the relevant part of the Register.
B.5	There must be an adequate number of appropriately qualified, experienced and, where required, registered staff in place to deliver an effective programme.
B.6	Subject areas must be taught by staff with relevant specialist expertise and knowledge.
B.7	A programme for staff development must be in place to ensure continuing professional and research development.
B.8	The resources to support student learning in all settings must be effectively used.
B.9	The resources to support student learning in all settings must effectively support the required learning and teaching activities of the programme.

¹⁰ Throughout this document, 'students' means registered orthoptists completing a training programme in the use of exemptions.

B.10	The learning resources, including IT facilities, must be appropriate to the curriculum and must be readily available to students and staff.
B.11	There must be adequate and accessible facilities to support the welfare and wellbeing of students in all settings.
B.12	There must be a system of academic and pastoral student support in place.
B.13	There must be a student complaints process in place.
B.14	Throughout the course of the programme, the education provider must have identified where attendance is mandatory and must have associated monitoring mechanisms in place.
B.15	Service users and carers must be involved in the programme.

Curriculum	
C.1	The learning outcomes must ensure that those who successfully complete the programme meet the standards for orthoptists using exemptions in legislation for the sale, supply and administration of medicines.
C.2	The programme must reflect the philosophy, core values, skills and knowledge base as articulated in any relevant curriculum guidance.
C.3	Integration of theory and practice must be central to the curriculum.
C.4	The curriculum must remain relevant to current practice.
C.5	The curriculum must make sure that students understand the implications of the HCPC's standards of conduct, performance and ethics on their use of exemptions in legislation for the sale, supply and administration of medicines.
C.6	The delivery of the programme must support and develop autonomous and reflective thinking.
C.7	The delivery of the programme must encourage evidence-based practice.
C.8	The range of learning and teaching approaches used must be appropriate to the effective delivery of the curriculum.
C.9	When there is interprofessional learning the profession-specific skills and knowledge of each professional group must be adequately addressed.

Practice placements	
D.1	Practice placements must be integral to the programme.
D.2	The length of time spent in practice placements must be appropriate to support the delivery of the programme and the achievement of the learning outcomes.
D.3	The practice placements must provide a safe and supportive environment.

D.4	The education provider must maintain a thorough and effective system for approving and monitoring all practice placements.
D.5	There must be an adequate number of appropriately qualified, experienced and, where required, registered staff in the practice placements.
D.6	Practice placement educators must have relevant knowledge, skills and experience.
D.7	Practice placement educators must be appropriately registered, unless other arrangements are agreed.
D.8	There must be regular and effective collaboration between the education provider and the practice placement provider.
D.9	Students and practice placement educators must be fully prepared for the practice placement environment, which will include information about an understanding of: <ul style="list-style-type: none"> – the learning outcomes to be achieved; – the timings and the duration of any practice experience and associated records to be maintained; – expectations of professional conduct; – the professional standards which students must meet; – the assessment procedures including the implications of, and any action to be taken in the case of, failure to progress; and – communication and lines of responsibility.
D.10	Learning, teaching and supervision must encourage safe and effective practice, independent learning and professional conduct.
D.11	A range of learning and teaching methods that respect the rights and needs of service users and colleagues must be in place throughout practice placements.

Assessment	
E.1	The assessment strategy and design must ensure that the student who successfully completes the programme has met the standards for orthoptists using exemptions in legislation for the sale, supply and administration of medicines.
E.2	All assessments must provide a rigorous and effective process by which compliance with external-reference frameworks can be measured.
E.3	Professional standards must be integral to the assessment procedures in both the education setting and practice placement setting.
E.4	Assessment methods must be employed that measure the learning outcomes.
E.5	The measurement of student performance must be objective and ensure safe and effective use of exemptions in legislation for the sale, supply and administration of medicines.

E.6	There must be effective monitoring and evaluation mechanisms in place to ensure appropriate standards in the assessment.
E.7	Assessment regulations must clearly specify requirements for student progression and achievement within the programme.
E.8	Assessment regulations, or other relevant policies, must clearly specify requirements for approved programmes being the only programmes which contain any reference to an HCPC protected title or part of the Register in their named award.
E.9	Assessment regulations must clearly specify requirements for a procedure for the right of appeal for students.
E.10	Assessment regulations must clearly specify requirements for the appointment of at least one external examiner who must be appropriately experienced and qualified and, unless other arrangements are agreed, be from the relevant part of the HCPC Register.

Standards for orthoptists using exemptions in legislation for the sale, supply and administration of medicines

Orthoptists must:	
1	Understand pharmacodynamics, pharmacokinetics, pharmacology and therapeutics relevant to medicines use within their professional scope of practice and how these may be altered by certain characteristics
2	Understand the legal context relevant to the use of exemptions in legislation for the sale, supply and administration of medicines, as well as current local and national policy and guidance concerning medicines use
3	Understand the differences between the sale, supply and administration of medicines using exemptions, other supply / administration mechanisms and prescribing mechanisms
4	Understand the various pharmacological and non-pharmacological approaches to disease management relevant to their practice and the risks and benefits of each option
5	Understand the importance of shared decision-making with service users to encourage self-care and adherence with medicines advice
6	Be able to make a decision about whether to sell, supply or administer medicines using exemptions, based on a relevant examination, assessment and history taking
7	Be able to undertake a thorough, sensitive and detailed patient medical history, including an appropriate medication history
8	Be able to communicate information about medicines clearly with service users and others involved in their care
9	Be able to evaluate each potential treatment option with respect to an individual service user, taking into account relevant factors, the service user's circumstances, co-morbidities and other medicines taken
10	Be able to topically administer medicines as appropriate within their professional scope of practice
11	Be able to demonstrate safe use of medicines
12	Be able to undertake drug calculations accurately
13	Be able to monitor response to medicines and modify or cease treatment as appropriate within their professional scope of practice, including referral to another professional
14	Be able to identify adverse medicine reactions, interactions with other medicines and diseases and to take appropriate action
15	Be able to recognise different types of medication error and respond appropriately
16	Understand antimicrobial resistance and the roles of infection prevention and control