NHS England

# Consultation on proposals to allow orthoptists to sell, supply & administer medicines under exemptions within the Human Medicines Regulations (2012) across the United Kingdom

**Prepared by the Allied Health Professions Medicines Project Team**

**NHS England –February 2015**

| NHS England INFORMATION READER BOX | | |
|---|---|---|
| **Directorate** | | |
| **Medical** | Commissioning Operations | Patients and Information |
| Nursing | Trans. & Corp. Ops. | Commissioning Strategy |
| Finance | | |

| **Publications Gateway Reference:** | **03048** |
|---|---|
| **Document Purpose** | Consultations |
| **Document Name** | Consultation on proposals to allow orthoptists to sell, supply & administer medicines under exemptions within the Human Medicnes Regulations (2012) across the United Kingdom. |
| **Author** | NHS England Allied Health Professions (AHP) Medicines Project Team. |
| **Publication Date** | 26 February 2015 |
| **Target Audience** | CCG Clinical Leaders, CCG Accountable Officers, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, NHS England Regional Directors, NHS England Area Directors, Allied Health Professionals, GPs, Emergency Care Leads, NHS Trust CEs |
| **Additional Circulation List** | Local Authority CEs, Directors of Adult SSs, Patients, Public, Carers, Independent and Third Sector Organisations, Royal Colleges, Healthcare Professional Bodies, Council of Deans for Health, Healthcare Regulators., Directors of Finance, Communications Leads, Directors of Children's Services |
| **Description** | This consultation documment is one of four consultations taking place as part of the AHP Medicines Project to extend access to medicines by paramedics, radiographers, dietitians and orthoptists across the United Kingdom. |
| **Cross Reference** | N/A |
| **Superseded Docs** (if applicable) | N/A |
| **Action Required** | Responses to consultation. |
| **Timing / Deadlines** (if applicable) | **Responses to arrive no later than 24/04/15.** |
| **Contact Details for further information** | Helen Marriott<br>AHP Medicines Project Lead<br>NHS England<br>5W20, Quarry House, Leeds,<br>LS2 7UE<br>0113 825 4767 |

## Document Status

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**Consultation on proposals to allow orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012) across the United Kingdom**

The proposed changes to medicines legislation would apply throughout the United Kingdom. This consultation document has been developed in partnership with; the Northern Ireland Department of Health, Social Services and Public Safety; the Scottish Department of Health and Social Care; the Welsh Department of Health and Social Services; the Department of Health for England; and the Medicines and Healthcare Products Regulatory Agency.




# Contents

# 1 Executive summary

This consultation concerns proposals to allow orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012). The proposed changes to medicines legislation would apply throughout the United Kingdom, in any setting in which orthoptists work including the NHS, independent and voluntary sectors.

Exemptions are defined as a specific piece of law allowing certain listed medicines to be sold, supplied and/or administered to patients by identified health professional groups without the need for another appropriate prescribing or supply/administration mechanism. Exemptions are NOT a prescribing mechanism.

Allowing orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012) has many potential benefits to patients, commissioners and providers. It will support the creation of new effective pathways focussed on enhancing patient experience which will result in improved outcomes for patients by reducing delays in care, more timely access to medicines needed and improve the patient experience through greater convenience and choice. Orthoptists will also be better able to use their skills specific to their role. A change in legislation also has the potential to improve patient safety by reducing delays in care and creating clear lines of responsibility for decisions made regarding medicines.

An Allied Health Professions (AHPs) Prescribing and Medicines Supply Mechanisms Scoping Project was undertaken in 2009 to establish whether there was evidence of service and patient need to support extending access to medicines for AHPs. The project found there was a strong case in support of exemptions for the specific list of medications used in the diagnosis and treatment of disorders of binocular vision.

The NHS England AHP Medicines Project Team, in partnership with the British and Irish Orthoptic Society (BIOS) developed a case of need for the use of exemptions by orthoptists, based on improving quality of care for patients in relation to safety, clinical outcomes and experience, whilst also improving efficiency of service delivery and value for money. Approval of the cases of need was received from NHS England's Medical and Nursing Directorates Senior Management Teams in May 2014 and from the Non-Medical Prescribing Board in July 2014. The AHP Medicines Project Board was established in September 2014 to oversee the governance of the project, whilst providing support and guidance to this programme of work.

A number of supporting documents are provided alongside this consultation to inform consideration of the options and questions. These include: *Draft Practice Guidance for Orthoptists for the Supply and Administration of Medicines under Exemptions within the Human Medicines Regulations (2012)*, *Draft Outline Curriculum Framework for Education Programmes to Prepare Orthoptists to use Exemptions* and a *Consultation Stage Impact Assessment*. These documents will remain in draft form until the consultation closes, when amendments will be made in line with the responses received and final versions published as appropriate.

A summary of this consultation document is also available on the NHS England consultation hub website here and can also be requested in alternative formats, such as easy read, Welsh language, large print or audio. Please contact: enquiries.ahp@nhs.net

This consultation seeks responses to the following questions:

**Question 1:** Should amendments to legislation be made to allow orthoptists to sell, supply and administer particular medicines under exemptions within the Human Medicines Regulations (2012)?

**Question 2:** Do you agree with the proposed list of medicines that orthoptists would be able to sell, supply and administer under exemptions within the Human Medicines Regulations (2012)?

**Question 3:** Do you agree that the two antibiotics (Chloramphenicol and Fusidic acid) should be included in the list of medicines that orthoptists would be able to sell, supply and administer under exemptions within the Human Medicines Regulations (2012)?

**Question 4:** Do you have any additional information on any aspects not already considered as to why the proposal to allow orthoptists to sell, supply and administer particular medicines under exemptions within the Human Medicines Regulations (2012) SHOULD go forward?

**Question 5:** Do you have any additional information on any aspects not already considered as to why the proposal to allow orthoptists to sell, supply and administer particular medicines under exemptions within the Human Medicines Regulations (2012) SHOULD NOT go forward?

**Question 6:** Does the 'Consultation Stage Impact Assessment' give a realistic indication of the likely costs, benefits and risks of the proposal?

**Question 7:** Do you have any comments on the proposed practice guidance for orthoptists supplying and administering medicines under exemptions?

**Question 8:** Do you have any comments on the 'Draft Outline Curriculum Framework for Education Programmes to Prepare Orthoptists to Use Exemptions'?

**Question 9:** Do you have any comments on how this proposal may impact either positively or negatively on specific equality characteristics, particularly concerning: disability, ethnicity, gender, sexual orientation, age, religion or belief, and human rights?

**Question 10:** Do you have any comments on how this proposal may impact either positively or negatively on any specific groups, e.g. students, travellers, immigrants, children, offenders?

# 2 Purpose of the document

## 2.1 Introduction to the consultation

This consultation is in accordance with the Human Medicines Regulations (2012) concerning proposals to introduce specific exemptions from legislative restrictions to allow orthoptists to sell, supply and administer particular medicines directly to patients in the course of their professional practice. However, this is subject to successful completion of an approved training programme and annotation of their professional registration with the Health and Care Professions Council (HCPC). The proposals would be achieved by amendment to the Human Medicines Regulations (2012).

Exemptions are defined as a specific piece of law allowing certain listed medicines to be sold, supplied and/or administered to patients by identified health professional groups without the need for another appropriate prescribing or supply/administration mechanism. Exemptions are NOT a prescribing mechanism.

This consultation document has been produced by NHS England with support from the BIOS, the MHRA, the Department of Health (DH), the Northern Ireland Department of Health, Social Services and Public Safety, the Scottish Department of Health and Social Care and the Welsh Department of Health and Social Services.

### Application to England, Wales, Scotland and Northern Ireland

The proposed changes to medicines legislation would apply throughout the United Kingdom, in any setting in which orthoptists work including the NHS, independent and voluntary sectors.

### The Professional Body

BIOS is the professional body representing orthoptists in the United Kingdom and Southern Ireland. The organisation also represents orthoptic assistants. The role is summarised in Appendix A for information.

### Who can respond to this consultation?

Everyone is welcome to respond. We hope to hear from the public, patients/patient representative groups, carers, voluntary organisations, healthcare providers, commissioners, doctors, pharmacists, AHPs, nurses, regulators, non-medical prescribers, the Royal Colleges and other representative bodies.

### The consultation

Will run for eight weeks and will close on **24 April 2015**

# 3 Introduction to the orthoptic profession

## 3.1 General information

Orthoptists are statutory registered AHPs who diagnose and manage amblyopia (the reduction of vision in one or both eyes) and treat patients with ocular imbalance (squint) and double vision. There are currently 1,378 (as of January 2015) orthoptists registered with the HCPC.

Orthoptists are key members of the NHS eye care team, working closely with ophthalmologists and optometrists to assess and treat patients of all ages, from premature babies who need visual assessment to the elderly who may have ocular movement disorders. Orthoptists are recognised as experts in squints and have a lead role in the primary vision screening of children aged four to five years. They may also work with patients who have brain injuries, diabetes, stroke, retinal disease, learning difficulties and glaucoma. Management of such conditions may involve use of specialist equipment to undertake diagnostic tests, such as measures of eye pressure and assessments of the patient's field of vision.

In response to an increase in demand and service redesign, the role of the orthoptist has developed significantly in recent years, including the introduction of extended roles such as advanced orthoptic practitioners. Following pre-registration training, many orthoptists gain experience of a number of specialities within the scope of the orthoptic profession. They develop their skills through additional training and/or post-graduate education to become advanced practitioners, taking on responsibilities that would have otherwise been held by medical staff. Orthoptists are encouraged to seek opportunities for role development as long as there is a service need and they work competently within their individual scope of practice.

Examples of these include:

**Refraction**

The most common cause of squint and reduced vision in children is the need for spectacles. Traditionally, testing for spectacles within the hospital setting was carried out by ophthalmologists, although the need for more streamlined services has resulted in some orthoptists being trained to perform tests for spectacles (refractions). The teaching of this skill is now included in orthoptic undergraduate courses. For the test to be reliable in children, dilation of the pupils and relaxation of the focusing muscles (cycloplegia) is required through administration of eye drops.

**Glaucoma care**

40% of orthoptic departments are currently involved in glaucoma care, which involves both the screening of new referrals for the disease and monitoring of those already undergoing treatment. This requires the use of topical anaesthetic, dyes and dilating eye drops. In many cases, prompt and effective management is essential to avoid permanent visual loss.

**Retinal photography**

Orthoptists are increasingly involved in retinal care, including retinal photography and optical coherence tomography (OCT), which may require dilation of the pupils.

## 3.2 Where orthoptists work

Orthoptists work in a variety of settings across the UK, from single-handed community clinics to large multidisciplinary clinics in acute hospital settings. Orthoptists also work in specialist schools, private clinics and universities. The vast majority of orthoptists are primarily employed within the NHS, although a number of individuals also undertake work in the private sector while simultaneously holding a substantive NHS post. The BIOS estimates that 40% of members are involved in some form of private sector work.

## 3.3 How orthoptists are trained and regulated

Under-graduate training of orthoptists consists of an approved three or four-year university degree-level course leading to a BSc or BMedSci in Orthoptics. Currently, these qualifications are offered at three UK universities.

Orthoptists are AHPs and are a statutorily regulated health profession under the terms of the Health and Social Work Professions Order (2001). The regulatory body is the HCPC. Any person wishing to use the protected title ‘orthoptist’ must be registered on the relevant part of the register. The HCPC sets the standards that all orthoptists have to meet in relation to their education, proficiency, conduct, performance, character and health. These are the minimum standards that the HCPC considers necessary to protect members of the public. Registrants must meet all these standards when they first register and complete a professional declaration every two years thereafter, to confirm they have continued to practise and continue to meet all the standards.

The HCPC regulates the fitness to practice and re-registration of those already on the register and has the powers to remove individuals from their register if the person falls below the standards required to ensure public safety. An orthoptist must undertake the necessary on-going training and experience to demonstrate that they are capable of working lawfully, safely and effectively within their given scope of practice and must not practise in areas where they are not proficient.

## 3.4 Current supply and administration of medicines by orthoptists

Under current medicines legislation, as autonomous practitioners, registered orthoptists make use of patient group directions (PGDs) and to a lesser extent patient specific directions (PSDs), to administer and supply a variety of preparations to the eye, for both diagnostic and therapeutic purposes.

- **A Patient Group Direction (PGD)** is a written instruction for the supply and/or administration of a licensed medicine (or medicines) in an identified clinical situation, where the patient may not be individually identified before presenting for treatment. Each PGD must be signed by both a doctor and pharmacist; and approved by the organisation in which it is to be used.
- **A Patient Specific Direction (PSD)** is a prescriber's (usually written) instruction that enables an orthoptist to supply or administer a medicine to a named patient. (see appendix B for further details of mechanisms)

Current supply and administration mechanisms work well when a PGD is in place and the patient falls within a predictable criteria, though have limitations in relation to access, equality and choice for patients.

## 3.5 Education programmes for orthoptists training to sell, supply and administer medicines under specific exemptions within the Human Medicines Regulations (2012)

Where there is an identified need for orthoptists to sell, supply and administer medicines under specific exemptions from medicines restrictions they would be required to gain entry to and successfully complete an HCPC approved training programme before gaining annotation on the HCPC register.

*A Draft Outline Curriculum Framework for Education Programmes to Prepare Orthoptists to Use Exemptions* can be accessed on the NHS England consultation hub website here. The HCPC have the authority to approve and monitor education programmes against the standards it sets.

## 3.6 Eligibility criteria for orthoptists wishing to train to sell, supply and administer medicines under specific exemptions within the Human Medicines Regulations (2012)

Not all orthoptists would be expected to train to use exemptions. It is proposed that all entrants to the training programme would need to meet the following requirements:

- Be registered with the Health and Care Professions Council as an orthoptist
- Be practising in an environment where there is an identified need for the individual to regularly use exemptions
- Be able to demonstrate support from their employer
- Be able to demonstrate medicines and clinical governance arrangements are in place to support safe and effective use of exemptions
- Be able to demonstrate how they reflect on their own performance and take responsibility for their own CPD, including networks for support, reflection and learning
- Provide evidence of a Disclosure and Barring Service (DBS) check within the last 3 years

Orthoptists using exemptions would be required to have an annotation on the HCPC register. This would require them to undertake appropriate steps to maintain their skills and competence in keeping with new standards for the use of exemptions, which will be developed by the HCPC if amendments to medicines legislation are made.

## 3.7 Continuing professional development (CPD)

Once registered, orthoptists must undertake CPD and demonstrate that they continue to practise both safely and effectively within their changing scope of practice, in order to retain their registration. The HCPC sets standards for CPD which all registrants must meet. Registrants are required to maintain a continuous, up-to-date and accurate portfolio of their CPD activities, which must demonstrate a mixture of learning activities relevant to current or future practice. The portfolio declares how CPD has contributed to both the quality of their practice and service delivery, whilst providing evidence as to how their CPD has benefited the service user.

The BIOS, the professional body for UK orthoptists, supports the HCPC in its requirement for orthoptists to engage in CPD and makes recommendations to its members regarding CPD activities required to achieve the standards set by the regulator.

The HCPC randomly audits the CPD of 2.5% of each registered profession on a 2-year cycle of registration renewal. Those registrants who are chosen for audit must submit a profile to show how their CPD meets the minimum standards of the regulator. If introduced, orthoptists qualified to use exemptions would have a similar responsibility to keep up to date with clinical and professional developments in medicines use.

In addition BIOS makes it clear to orthoptists that they are required to maintain their competence to practise. This is an individual professional requirement and the employing authority would have a role in monitoring that this is the case by, e.g. undertaking annual appraisal interviews.

Examples of CPD activities for orthoptists include:

- Peer review
- Peer supervising and teaching
- Attending regular meetings
- Attending BIOS study days
- Recording self-reflection
- Presenting at conferences
- Membership of BIOS Special Interest Groups
- NHS Information Governance (IG) Training Tool

## 3.8 Governance and safeguarding

The role of the HCPC is to protect the public. It does this by setting standards for an orthoptist's education, training, competence, conduct, behaviour and health. An orthoptist must be registered with the HCPC to practise within the UK and must meet the standards set. The HCPC can take action to protect the public where orthoptists do not meet the necessary standards, including removing them from practice where appropriate. The HCPC will set standards for the use of exemptions and will approve the educational programmes that will deliver training to make sure that the programmes meet the necessary standards. An orthoptist would only be able to use exemptions if they met the entry requirements to train and successfully complete an educational programme to then have their entry on the HCPC Register 'annotated'.

By setting standards, approving programmes and annotating the register, the HCPC can ensure that orthoptists meet the standards necessary for safe and effective use of medicines via exemptions. All professionals registered with the HCPC, including orthoptists, must always practise within their 'scope of practice'. An orthoptists scope of practice is the area of practice in which they have the knowledge, skills and experience to practise safely and effectively. This requirement would extend to an orthoptists use of medicines under exemptions within the Human Medicines Regulations (2012). This means an orthoptist must only supply and/or administer medicines under exemptions where they have the appropriate knowledge, skills and experience to do so safely. If they used medicines outside of their scope of practice, the HCPC could take action against them to protect the public.

The HCPC's requirements cover orthoptists working both in the public and private sector. This means that even if an orthoptist is working as a sole independent practitioner, they must still undertake CPD and work only within their scope of practice. Orthoptists working in NHS settings will be governed by the policies and procedures of their NHS employer with regard to medicines governance. Where orthoptists wish to use exemptions in private practice they are required to have similar governance policies and procedures in place.

The BIOS is the only professional body dedicated to representing orthoptists. Their focus is to ensure continued support of high quality, current evidence-based practice. Competency standards[1] and professional practice guidelines for the extended role of the orthoptist[2] have been developed to support this.

Employers will retain responsibility for ensuring adequate skills, safety and appropriate environments are in place for orthoptists using exemptions. Employers would also be responsible for ensuring that there is a need for an orthoptist to undertake further supply and administration responsibilities, prior to their commencement of training and ensure that there is a role to use exemptions post-training. The same standards would apply regardless of whether the orthoptist is working in the NHS, independent or other settings.

Orthoptists should also undertake information governance training as prescribed by the Health and Social Care Information Centre's (HSCIC) Information Governance Toolkit using the NHS Information Governance Training Tool.

### 3.8.1 Access to medical records

In the interests of patient safety, it is essential that orthoptists using exemptions (if implemented) ensure they have up-to-date, relevant and proportionate information about a patient's medical history and medicines. Orthoptists mostly work in the hospital or community clinic setting and have access to the patient's hospital notes. That access will normally be with implied consent as orthoptists are part of the team providing the treatment or care in question. However, where the patient has refused access or the information is especially sensitive explicit consent should be sought. Orthoptists must assure themselves that they have all relevant information in relation to the safe supply and administration of medicines for the individual patient and if there is any doubt, further information should be sought before making a decision whether to supply or administer medicines to the patient. When necessary it should be explained to patients that all or part of the treatment cannot be given unless they grant access to the information.

### 3.8.2 Updating the medical record

It is essential that any supply of medicine for treatment purposes is known to other healthcare professionals caring for the same patient, such as the patient's GP, and that the patient is aware or where necessary is made aware of this. All orthoptists supplying medicines are expected to update a patient's notes with their decisions contemporaneously, wherever possible and in any event, within 48 hours of the episode of care. This may be done electronically, via secure e-mail or electronic update to the GP's office where the patient's notes are held, or by fax to the GP's surgery,

[1] BIOS (revised 2014), *Competency Standards and Professional Practice Guidelines* http://www.orthoptics.org.uk
[2] BIOS (2014), *Competency Standards for Extended Roles* http://www.orthoptics.org.uk

always following good information governance procedures to ensure its safe transfer, whilst meeting local information governance requirements. The Health and Social Care Information Centre have produced a detailed *Information Governance Toolkit*[3] regarding the safe transfer of patient data which lists the most commonly used methods of communication along with the minimum standards required for safe and secure data transfer, which should be followed.

### 3.8.3 Clinical Governance

Part of the assurance to be put in place for satisfying local clinical governance requirements will be the development of a policy for the use of exemptions by orthoptists that is approved according to local arrangements and frequently monitored/reviewed. This may include strategic planning, risk management, evaluation of clinical governance, medicines management, organisational change and innovative service redesign using exemptions.

### 3.8.4 Antimicrobial Stewardship

Healthcare workers have a vital role to play in preserving the usefulness of antimicrobials by controlling and preventing the spread of infections that could require antibiotic treatment. All orthoptists supplying or administering medicines will be required to work within their scope of practice and competence. Medicines management is not an activity that occurs in isolation so orthoptists using exemptions will communicate with other practitioners involved in the care of patients. They will also be required to consider antimicrobial stewardship and follow local policies for antibiotic use. The local policy is required to be based on national guidance and should be evidence based, relevant to the local healthcare setting and take in to account local antibiotic resistance patterns. The local policy should also cover diagnosis and treatment of common infections and prophylaxis of infection. Orthoptists should also follow the 2013 Public Health England (PHE)/ Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) *Antimicrobial Prescribing and Stewardship Competencies*[4].

[3] Health and Social Care Information Centre: *IG Toolkit*. https://www.igt.hscic.gov.uk/
[4] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies* https://www.gov.uk/government/publications/antimicrobial-prescribing-and-stewardship-competencies

# 4 Benefits

Extension of the supply and administration of medicines under exemptions has been successfully applied to the podiatry, paramedic, optometry and midwifery professions.

The development of exemption use for orthoptists is part of a drive to make it easier for patients to have access to the medicines that they need, reduce inequalities (within access to medicines), improve the patient experience and make better use of the skills of orthoptists within the multi-disciplinary team in a time where there is an increasing demand on ophthalmology services. The extension of supply and administration mechanisms is an important part of developing health professionals' roles in delivering frontline care and patient-centred services.

For example**:**

- When children with reduced vision in one eye (amblyopia) require treatment, the orthoptist mainly offers patching as the first option. Pharmaceutical blurring of the better eye has been shown to be as effective[5] though is not offered as a first line treatment by many orthoptists due to a lack of access to this medicine.

If orthoptists were to have access to this medicine under exemptions within the Human Medicines Regulations (2012), patients could be offered atropine routinely as a first-line treatment option and would benefit from timely access to the right choice of treatment.

- PGDs are not transferable between NHS employing organisations, and completion of all relevant documentation and approval from the medicines management committee is required before a staff member can use them. When new members of staff wish to supply or administer medicines to patients they must do so by obtaining a PSD from a prescriber (usually an ophthalmologist). This may mean a return visit for patients/parents to collect medicines if no prescriber is present in clinic on that day.

Exemptions allow orthoptists to access the medicines they need to undertake their role, no matter where they are working or whom they are working with. They therefore support patients to access the right medicines at the right time, in the right place and without any unnecessary delay.

- Any variations in PGDs require relevant documentation and approval by the hospital's medicines management committee. Recent manufacturing changes have resulted in an existing medicine (proxymetacaine 0.5% with fluorescein 0.25%), which is covered by a PGD for many orthoptists, being discontinued. Until a new PGD is in place, the orthoptist will be reliant on an ophthalmologist as a prescriber for a PSD, to allow instillation of alternative medicines to facilitate testing.

Exemptions would allow orthoptists to have access to a range of medicines to ensure patients continue to have access to the type of medicines they require even when there is unavailability of a product.

[5] Pediatric Eye Disease Investigator Group (2005*) Two-year follow-up of a 6-month randomized trial of atropine vs patching for treatment of moderate amblyopia in children*. Archives of Ophthalmology, 123(2): 149-157 http://www.ncbi.nlm.nih.gov/pubmed/15710809

# 5 Approach to the consultation

## 5.1 The case for change

The extension of supply and administration mechanisms for healthcare professionals is part of a drive to make better use of their skills and to make it easier for patients to have access to the medicines that they need. The use of exemptions is an important part of developing health professionals' roles in delivering frontline care and patient-centred services.

The introduction of exemptions within the Human Medicines Regulations (2012) for orthoptists supports the achievement of a number of current ambitions across the UK:

**In England:** supports the achievement of ambitions set out in *Equity and Excellence: Liberating the NHS*[6], and the *NHS Five Year Forward View*[7].

**In Scotland:** supports the delivery of *Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision*[8] and *Improving Outcomes by Shifting the Balance of Care: Improvement Framework*[9].

**In Wales:** supports the achievement of ambitions set out in *Together for Health: A Five Year Vision for the NHS in Wales*[10] and *Achieving Excellence: The Quality Delivery Plan for the NHS in Wales*[11].

**In Northern Ireland:** supports the delivery of *Transforming Your Care: A Review of Health and Social care in Northern Ireland*[12] and *Transforming Your Care: Strategic Implementation Plan*[13]

## 5.2 Work to date

### 5.2.1 Scoping study[14]

An AHP Prescribing and Medicines Supply Mechanisms Scoping Project was undertaken in 2009 to establish whether there was evidence of service and patient need to support the extension of prescribing and medicines supply mechanisms available to AHPs.

The scoping project report found that AHPs use prescribing and medicines supply and administration mechanisms safely and effectively to improve patient care in clinical pathways and that application of the mechanisms are suited to the needs of patients.

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[6] Department of Health (2010) *Equity and Excellence: Liberating the NHS*, London
[7] NHS England (2014) *Five Year Forward View*, London
[8] NHS Scotland (2011*) Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision,* Edinburgh
[9] NHS Scotland (2009) *Improving Outcomes by Shifting the Balance of Care: Improvement Framework,* Edinburgh
[10] NHS Wales (2011) *Together for Health: A Five Year Vision for the NHS in Wales,* Cardiff
[11] NHS Wales (2012) *Achieving Excellence: The Quality Delivery Plan for the NHS in Wales,* Cardiff
[12] Northern Ireland Department of Health, Social Services and Public Safety (2011) *Transforming Your Care: A Review of Health and Social Care in Northern Ireland,* Belfast
[13] Northern Ireland Department of Health, Social Services and Public Safety (2013) *Transforming Your Care: Strategic Implementation Plan,* Belfast
[14] Department of Health (2009). A*llied Health Professionals Prescribing and Medicines Supply Mechanisms Scoping Project Report*. London, DH. http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_103948

The project also found that extension of prescribing and medicines supply for certain AHPs would improve the patient experience by allowing patients greater access, convenience and choice. The project found a strong case for extending the supply and administration mechanisms to orthoptists under exemptions.

### 5.2.2 Developing the case of need

An AHP Medicines Project Team was established within NHS England in October 2013 to take this work forward under the Chief Allied Health Professions Officer within NHS England. The NHS England AHP Medicines Project Team, in partnership with the BIOS, developed a case of need towards the introduction of exemptions for orthoptists. This was based on improving quality of care for patients in relation to safety, choice, clinical outcomes and experience, whilst also improving efficiency of service delivery and value for money. Approval of the case of need was received from NHS England's Medical and Nursing Directorates Senior Management Teams in May 2014 and from the DH Non-Medical Prescribing Board in July 2014.

# 6 Proposal for use of exemptions by orthoptists

Provided it is in the course of their professional practice, orthoptists annotated to use exemptions will be able to sell, supply or administer the following medicines in the form of eye drops or ointment for topical administration, for any condition within their scope of practice and competence:

- Atropine
- Cyclopentolate
- Tropicamide
- Lidocaine with fluorescein
- Oxybuprocaine
- Proxymetacaine
- Tetracaine
- Chloramphenicol
- Fusidic acid
- Sodium cromoglicate

In addition, non-prescription medicines for supply and administration in the course of professional practice (e.g. phenylephrine 2.5%, fluorescein and ocular lubricants)

**Benefits**

Patients in contact with appropriately trained orthoptists would be able to receive the care and medicines they need, without having to make additional appointments with prescribers. A greater number of patients could benefit from improved care, first time and in the right place. The responsibility for supplying or administering medicines within competence would be clearly with the eligible orthoptist themselves.

**Limitations**

This option has no obvious limitations.

**Question 1:** Should amendments to legislation be made to allow orthoptists to sell, supply and administer particular medicines under exemptions within the Human Medicines Regulations (2012)?

**Question 2:** Do you agree with the proposed list of medicines that orthoptists would be able to sell, supply and administer under exemptions within the Human Medicines Regulations (2012)?

## 6.1 Inclusion of antibiotics

Orthoptists are specialists in children's eye care. Patients, especially children, who are being treated by orthoptists for squints/spectacle prescriptions often present with eye infections. It is important that orthoptists are able to offer care in the right place at the right time to optimise patient outcomes and their experience of the care received. Where a PGD is unavailable or the patient falls outside the criteria of the PGD, under current arrangements the orthoptist will have to obtain a PSD from a prescriber to supply the medicine or, in the case of chloramphenicol, advise the patient/parent to obtain the medicine over-the-counter from a pharmacist (chloramphenicol is available as a P medicine in ointment form). This then results in potential delays to treatment and/or additional appointments if a prescriber is not available in clinic at that time.

The Royal College of Ophthalmologists supports the inclusion of more than one antibiotic on the list of exemptions for orthoptists to ensure that where there is a recorded allergy, previous reaction or contraindication to use chloramphenicol ointment, then there is an alternative option for the orthoptist to provide Fusidic acid. If neither can be used, then medical input should be obtained. This will promote access to timely treatment of bacterial eye infections thereby reducing the potential for complications and improve patient experience.

**Question 3:** Do you agree that the two antibiotics (Chloramphenicol and Fusidic acid) should be included in the list of medicines that orthoptists would be able to sell, supply and administer under exemptions within the Human Medicines Regulations (2012)?

## 6.2 Additional information

The following questions invite additional information relevant to this proposal:

**Question 4:** Do you have any additional information on any aspects not already considered as to why the proposal to allow orthoptists to sell, supply and administer particular medicines under exemptions within the Human Medicines Regulations (2012) SHOULD go forward?

**Question 5:** Do you have any additional information on any aspects not already considered as to why the proposal to allow orthoptists to sell, supply and administer particular medicines under exemptions within the Human Medicines Regulations (2012) SHOULD NOT go forward?

## 6.3 Supporting documents: impact assessment, practice guidance and education curriculum framework

### 6.3.1 Impact assessment

Impact assessments are an integral part of the policy making process. The purpose of an impact assessment is to focus on why intervention is necessary, what impact the policy change is likely to have, the highlighting of costs, benefits and risks. *The Consultation Stage Impact Assessment* is available on the NHS England consultation hub website here and contains the available evidence of the actual (where available) or estimated costs and benefits for the introduction of exemptions from the Human Medicines Regulations (2012) by orthoptists. The consultation is an opportunity to gather additional evidence to further inform the costs, benefits and risks of the proposal.

**Question 6:** Does the 'Consultation Stage Impact Assessment' give a realistic indication of the likely costs, benefits and risks of the proposal?

### 6.3.2 Practice guidance

The proposed practice guidance for orthoptists supplying and administering medicines under exemptions, has been developed by the British and Irish Orthoptic Society and provides information which should underpin the decision-making and actions of orthoptists who are annotated with the Health and Care Professions Council (HCPC) as holding 'exemption rights' to be able to sell, supply and administer listed prescription only medicines (POMs) and pharmacy (P) medicines. The proposed practice guidance can be accessed on the NHS England consultation hub website here.

This document is 'guidance'. Guidance is information which an orthoptist has a duty to consider and is expected to take into account as part of their decision making process. The practice guidance document also provides advice on the behaviours and conduct expected of orthoptists who are annotated on the HCPC register as able to use exemptions. An orthoptist using exemptions will be expected to justify any decision to act outside the terms of the practice guidance and, in particular, if the orthoptist undertakes a course of action not recommended by this guidance there must be robust reasons for doing so.

The advice in this document applies to all sectors of health and social care provision in the United Kingdom where medicines use occurs. The consultation is an opportunity to acquire feedback and comments on the guidance developed and therefore the practice guidance document will remain in draft form until the consultation closes, when amendments will be made in line with the responses received and final versions published as appropriate.

**Question 7:** Do you have any comments on the proposed practice guidance for orthoptists supplying and administering medicines under exemptions?

### 6.3.3 Education curriculum framework

The British and Irish Orthoptic Society has developed a draft outline curriculum framework for education programmes to prepare orthoptists to use exemptions aimed at education providers intending to develop education programmes and individuals interested in education programmes for orthoptists to fulfil the requirements for annotation on the HCPC register as qualified to use exemptions within the Human Medicines Regulations (2012) to sell, supply and administer medicines. The *Draft Outline Curriculum Framework for Education Programmes to Prepare Orthoptists to Use Exemptions* can be accessed on the NHS England consultation hub website here.

The programmes will be subject to approval and monitoring by the HCPC against the standards that it sets. Individuals who successfully complete an approved programme are able to apply for annotation on the HCPC register as qualified to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012) to sell, supply and administer medicines.

The consultation is an opportunity to gain feedback and comments on the outline curriculum framework which will remain in draft form until the consultation closes, when amendments will be made in line with the responses received and final versions published as appropriate.

**Question 8.** Do you have any comments on the 'Draft Outline Curriculum Framework for Education Programmes to Prepare Orthoptists to Use Exemptions'?

## 6.4 Equality

Orthoptists have a responsibility to contribute to equality in healthcare by working towards eliminating discrimination and reducing inequalities in care. The BIOS, communicates clear values and principles about equality and fairness. All members of the orthoptic workforce are required to work within the Code of Ethics, which makes clear these expectations.

Discussions held with key stakeholders, including the professional bodies, regulators, MHRA, DH, clinicians from: pharmacy, podiatry, physiotherapy, radiography, dietetics and orthoptics; service managers; educationalists, commissioners and service users highlighted potential for the use of exemptions by orthoptists to improve access to medicines for groups within the community and in particular, within rural areas. The introduction of exemptions for orthoptists also has the potential to streamline care for other groups including children.

At present, orthoptists are restricted by the requirement for a prescriber, usually an ophthalmologist, to prescribe the medicines patients require if the current supply and administration mechanisms available to them are not sufficient. This involves additional appointments and delays in patients receiving the required medications. This is particularly problematic in rural and remote communities where access to an ophthalmologist may not be practical.

The introduction of exemptions for orthoptists would enable innovative care pathway redesign. An orthoptist using exemptions would be able to ‘see and treat’ some patients directly and supply the required medications at the time, reducing cost, time and travel for patients. This will be particularly beneficial for groups in rural and remote locations, travellers, small community hospitals or specialist clinics and services.

Specific groups such as children and people with disabilities can benefit through avoiding the need for delay or additional appointments to obtain a prescription. Orthoptists using exemptions can play a role in delivering services for such groups.

As autonomous practitioners, orthoptists using exemptions would be able to work in a much more flexible way. As the proposed changes to regulations will improve access to services and the way in which services can be delivered, it is assumed that there will be a benefit to any existing inequalities. Within a local context, service providers and commissioners can use service redesign to address specific characteristics of equality and the needs of specific groups.

**Question 9:** Do you have any comments on how this proposal may impact either positively or negatively on specific equality characteristics, particularly concerning: Disability, ethnicity, gender, sexual orientation, age, religion or belief, and human rights?

**Question 10:** Do you have any comments on how this proposal may impact either positively or negatively on any specific groups, e.g. students, travellers, immigrants, children, offenders?

# 7 Consultation process

## 7.1 How to respond

You can respond in one of the following ways:

- By completing the **online consultation** here
- Download and print a copy of the consultation response form here. Send your responses to George Hilton, AHP Medicines Project Team, NHS England, 5W20, Quarry House, Leeds, LS2 7UE
- Alternatively, you may request a copy of the consultation response form to be posted to you. Please contact: enquiries.ahp@nhs.net

A summary version of this consultation document is also available here and can be requested in alternative formats, such as easy read, Welsh language, large print and audio. Please contact enquiries.ahp@nhs.net

This consultation will run for eight weeks and responses should be sent to arrive no later than **24 April 2015**

## 7.2 Comments on the consultation process itself

If you have any concerns or comments which you would like to share relating specifically to the consultation process itself please contact -

**Address*:** George Hilton
AHP Medicines Project Team
NHS England
5W20, Quarry House
Leeds
LS2 7UE

**e-mail:** enquiries.ahp@nhs.net

***Please do not send consultation responses to this address**

# 8 Next steps

Following the close of the consultation, the CHM will be asked to consider the proposals in light of comments received. CHM's advice will be conveyed to Ministers. Subject to the agreement of Ministers, the MHRA will then make the necessary amendments to medicines legislation.

If all elements of the proposal are approved and all relevant organisations are in a position to complete their elements of the work at the earliest possible point without delay, the first intake of orthoptists on an exemptions education programme could be in late 2016.

Part of the drive to allow orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012) is the opportunities it gives for service re-design to improve patient centred practice. NHS England will be working with partners including the Devolved Administrations, and in particular, commissioners to steer the necessary changes.

# 9 Appendices

## 9.1 Appendix A: Role of the professional body

The BIOS is the only professional body dedicated to representing UK Orthoptists and currently has 1473 members (as of December 2014). The BIOS focus is to ensure continued support of high quality, current evidence-based practice. This includes representation at strategic level in all 4 countries and Ireland ensuring decision-making in eye health represents the role and competencies of Orthoptists. CPD is provided through postgraduate education, training and research. BIOS supports new graduates through preceptorship, and autonomous practitioners through special interest groups, extended roles and advanced practice competencies accredited by BIOS. Their work also includes promotion of the profession and representation of members.

The Society further represents the interests of orthoptists through membership of appropriate committees and advisory groups, by developing professional standards guidance, and by responding to consultation documents and requests for advice from government, and other professional and registrant bodies.

**http://www.orthoptics.org.uk**

## 9.2 Appendix B: Mechanisms for the supply and administration of medicines

The mechanisms available for the supply and administration of medicines are:

- Patient Specific Directions (PSDs)
- Patient Group Directions (PGDs)
- Specific Exemptions from medicines legislation covering supply or administration

### Patient Specific Direction (PSD)

A Patient Specific Direction is a traditional written instruction, from a prescriber, for medicines to be supplied or administered to a named patient. The majority of medicines are still supplied or administered using this process.

All allied health professionals (AHPs), including orthoptists, can supply or administer a medicine following a patient-specific direction from a prescriber.

### Patient Group Directions (PGDs)

A Patient Group Direction (PGD) is a written instruction for the supply or administration of a licensed medicine (or medicines) in an identified clinical situation, where the patient may, or may not, be individually identified before presenting for treatment. This should not be interpreted as indicating that the patient must not be identified; patients may or may not be identified, depending on the circumstances.

A PGD is authorised by a doctor and a pharmacist and must meet certain legal criteria. Each PGD must be approved by the organisation in which it is to be used. PGDs can also be developed in specific non-NHS settings such as independent hospitals and clinics registered with the Care Quality Commission and prisons.

PGDs can be used for the supply or administration of medicines by a number of healthcare professions, including orthoptists.

### Specific Exemptions Covering Supply or Administration

A number of health professions, e.g. midwives, podiatrists, optometrists and paramedics have specific exemptions in medicines legislation to sell, supply or administer medicines. An exemption enables the relevant health professional to sell or supply the specific medicine listed in the exemption without a prescription, e.g. registered podiatrists have exemptions under medicines legislation for parenteral administration of a number of prescription only medicines (POMs), including local anaesthetics and some painkillers.

## 9.3 Appendix C: Contributors

**Membership of NHS England Allied Health Professions Medicines Project Board**

| Representative | Organisation |
|---|---|
| Lesley-Anne Baxter | Allied Health Professions Federation |
| Charlotte Beardmore | Society and College of Radiographers |
| Jan Beattie | Scottish Government |
| Sarah Billington | Care Quality Commission |
| Julie Bishop | MHRA |
| Rebecca Blessing | Department of Health |
| Sara Bordoley | NHS England |
| Nicole Casey | Health and Care Professions Council |
| Bill Davidson | Patient and public representative |
| Hannah-Rose Douglas | NHS England |
| Anne Duffy | Department of Health, Social Services & Public Safety (Northern Ireland) |
| Catherine Duggan | Royal Pharmaceutical Society |
| Gerry Egan | College of Paramedics |
| Sue Faulding | Health and Social Care Information Centre |
| Katherine Gough | Dorset Clinical Commissioning Group |
| Linda Hindle | Public Health England |
| Barry Hunt | College of Paramedics (Advisory) |
| Steve Irving | Association of Ambulance Chief Executives |
| Cathryn James | Association of Ambulance Chief Executives |
| Elisabeth Jelfs | Council of Deans |
| Sue Kellie | British Dietetic Association |
| Helen Marriott (Project Lead) | NHS England |
| Rowena McNamara | British and Irish Orthoptic Society |
| Shelagh Morris | NHS England |
| Graham Prestwich | Patient and public representative |
| Suzanne Rastrick (Co-Chair) | NHS England |
| Patricia Saunders | Health Education England |
| Alison Strode | Welsh Government |
| Duncan Stroud | NHS England |
| Bruce Warner (Co-Chair) | NHS England |
| Hazel Winning | Department of Health, Social Services & Public Safety ((Northern Ireland) |

## 9.4 Appendix D: Frequently Asked Questions

### 1. What is an orthoptist?

Orthoptists are Allied Health Professionals (AHPs) whose core role is to diagnose and manage amblyopia (lazy eye) and treat patients with ocular imbalance (squint) and double vision. However, in response to an increased number of patients (or as examples of service redesign), orthoptists have become involved in extended / advanced practitioner roles, such as refraction (testing for spectacles), glaucoma assessment and retinal photography, contributing significant improvements within service development.

### 2. What are exemptions?

Exemptions are defined as a specific piece of law allowing certain listed medicines to be sold, supplied and/or administered to patients by identified health professional groups without the need for another appropriate prescribing or supply/administration mechanism. Exemptions are NOT a prescribing mechanism

### 3. What are the current arrangements for the supply and administration of medicines by AHPs?

Patient Group Directions for the supply and administration of medicine are available to all AHPs, with the exception of art therapists, music therapists and dramatherapists. All the professions can supply and administer medicines via Patient Specific Directions. Within the AHPs exemptions are currently used by podiatrists and paramedics

### 4. Why are exemptions for orthoptists needed?

There are many potential benefits for patients, commissioners and health care providers. In some clinical pathways, the scope of the existing legislation fits well with the needs of patients and enables optimal care. For example, current mechanisms for the supply and administration of medicines by orthoptists (via PGDs) work well for patients requiring pupil dilation where they have light coloured eyes and respond well to first-line diagnostic drops. Existing arrangements do not best support the needs of patients, particularly those who require treatment for lazy eye (amblyopia) as the choice of treatment for these patients is limited by the inaccessibility of an eye drop, which is as effective as wearing a patch.

PGDs are very time-consuming to organise, demand much time from prescribing colleagues and result in inequalities of care between hospitals and different patient groups as they are derived locally, not nationally, and so differ between hospitals. Where patients require medicines management outside that specified in a PGD, a prescriber (normally an Ophthalmologist) would need to be involved in their diagnosis or treatment. The existing arrangements result in unnecessary delays, put patients at risk (especially vulnerable groups such as children) and are costly to administer.

With exemptions, the creation of innovative new care pathways will be supported, resulting in improved outcomes for patients by reducing delays in care, improving compliance in using medicines and improving patient experience through increased access, convenience, choice and productivity within multi-disciplinary teams, especially in a time where there is an increasing demand for ophthalmology services.

**5. Why have exemptions for orthoptists not been proposed before now?**

*The AHP Prescribing and Medicines Supply Mechanisms Scoping Project Report*[15] found a strong case for orthoptists to be able to sell, supply and/or administer medicines under exemptions within the Human Medicines Regulations (2012) and recommended that further work be undertaken, when appropriate. Due to increasing service requirements (e.g. the increasing numbers of patients with glaucoma) and the need for more efficient, high quality patient-centred care, the policy drivers for establishing a specific list of exemptions for orthoptists are stronger now than ever before. Therefore resources within NHS England and BIOS have been allocated to take this work forward to public consultation.

**6. Will *all* orthoptists be able to use exemptions?**

Only orthoptists who are currently registered to practice and who have an identified clinical need for exemptions within their practice will be eligible to train to use exemptions. The medicines included in the proposed list of exemptions are the most commonly used by orthoptists.

**7. What training will orthoptists receive in order to be able to use exemptions?**

Comprehensive education programmes to be approved by the HCPC will be put in place to ensure that orthoptists are sufficiently competent, confident and educated to supply and administer medicines under exemptions. A draft outline curriculum framework has been developed for the training of orthoptists to use exemptions and can be found on the NHS England consultation hub website here. Not all orthoptists meet the entry requirements for training. In the future, it may be possible for the training to be embedded in to the undergraduate programme for orthoptics so that new members of the profession would be trained to use exemptions as part of their degree. This is in line with the podiatry, optometry and midwifery professions.

**8. Is it safe to allow orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012)?**

Patient safety remains of paramount importance. Orthoptists have a long history of supplying and administering medicines via PGDs and PSDs.

If changes of legislation occur, the HCPC will develop new standards for the use of exemptions. Orthoptists using exemptions will be professionally responsible for their own actions. They are required to work within their employers' clinical governance frameworks and are accountable for their actions to both their employers and regulatory bodies. Once trained, individuals will be required to keep their skills up to date.

Extending access to medicines supply mechanisms has the potential to improve patient safety by reducing delays in care, improving compliance with medicines and supporting clear lines of professional responsibility.

[15] Department of Health (2009) A*llied Health Professionals Prescribing and Medicines Supply Mechanisms Scoping Project Report*. London, DH. http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_103948

### 9. Will orthoptists using exemptions be able to supply and administer medicines for children?

Orthoptists using exemptions will be able to supply and administer medicines for children within their paediatric scope of practice and competence. Orthoptists have experience in supply and administration of medicines for children via PGDs and PSDs. In addition, local and national policies and procedures would be followed which address medicine management issues in paediatrics.

### 10. Which medicines will orthoptists be able to supply and administer under exemptions within the Human Medicines Regulations (2012)?

Subject to changes in legislation, appropriately qualified and annotated orthoptists will be able to supply and/or administer any medicine included on the agreed Medicines List (see section 6), provided it falls within their individual area of competence and respective scope of practice.

### 11. How do we ensure the use of exemptions by orthoptists will not increase antimicrobial resistance and contribute to over supplying of medication?

Healthcare workers have a vital role to play in preserving the usefulness of antimicrobials by controlling and preventing the spread of microbes. All orthoptists supplying medicines via exemptions will be required to work within their scope of practice and the 2013 Public Health England (PHE)/ Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) *Antimicrobial Prescribing and Stewardship Competencies*[16] and are professionally responsible for ensuring that they adhere to standards of supply and administration of all medicines, as set by the MHRA and NICE. They will also be required to follow local policies for antimicrobial use. This is a specific competence included in the *Draft Outline Curriculum Framework for Education Programmes to Prepare Orthoptists to use Exemptions,* which the HCPC will use to approve training programmes. Medicines supply is not an activity that occurs in isolation, so orthoptists supplying medicines via exemptions will communicate with other practitioners involved in the care of patients.

### 12. How will an orthoptist communicate their decisions to other practitioners involved in a patients care?

Orthoptists supplying and/or administering medicines to patients under exemptions will need to communicate effectively with other practitioners involved in the patients care within and across the boundaries of NHS and private practice, and use the most appropriate media available. When sending patient data, it is vital that the data is secure and that the risk of data loss (including misdirection) is minimised.

The Health and Social Care Information Centre gives detailed guidance on information security[17], and detailed and regularly updated information security requirements are set out in the HSCIC's Information Governance Toolkit[18].

[16] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies* https://www.gov.uk/government/publications/antimicrobial-prescribing-and-stewardship-competencies
[17] Health and Social Care Information Centre: *Principles of information security* http://systems.hscic.gov.uk/infogov/security
[18] Health and Social Care Information Centre: *IG Toolkit*. https://www.igt.hscic.gov.uk/

**13. On the entry requirements for the education programmes, the Disclosure and Barring Service (DBS) requirement is to "*provide evidence of a DBS check within the last 3 years*" - Why is this?**

The Criminal Records Bureau (CRB) and the Independent Safeguarding Authority (ISA) have merged to become the Disclosure and Barring Service (DBS). The DBS enables organisations in the public, private and voluntary sectors to make safer recruitment decisions by identifying candidates who may be unsuitable for certain work, especially involving children or vulnerable adults.

Entry requirements for nurses and pharmacists undertaking courses to extend their access to medicines via independent prescribing include the need to provide proof of a DBS check undertaken within the last three years. This requirement will bring orthoptists in line with the requirements of nurses and pharmacists.

**14. How will orthoptists using exemptions maintain their competency in the use of medicines?**

Practising orthoptists are required to undertake CPD relevant to their practice to maintain and demonstrate continuing competence. To maintain registration with the HCPC, orthoptists must sign a professional declaration once every two years to confirm that they continue to meet the HCPC's standards of proficiency for safe and effective practice, and that they meet the HCPC's standards for continuing professional development.

Examples of CPD for orthoptists include:

- Peer review
- Peer supervising and teaching
- Attending regular meetings
- Attending BIOS study days
- Recording self-reflection
- Presenting at conferences
- Membership of BIOS Special Interest Groups
- Orthoptists working within the NHS also require annual appraisals, of which medicines management will be a part.

**15. Will orthoptists working outside the NHS be able to train to use exemptions?**

Yes, provided they meet the entry requirements of the education programme, including demonstration that they have appropriate governance arrangements in place for their role as an orthoptist using exemptions.

**16. How will an HCPC registered orthoptist be annotated to indicate that they are qualified to use exemptions?**

If changes in legislation occur, the HCPC Register will be annotated to show that an individual has successfully completed post-registration training. The HCPC annotates the register based on information provided by education providers. The HCPC will only annotate individuals who successfully complete the training and pass the required assessment; those who do not complete the training or pass the required assessment (and therefore do not meet the necessary standards) cannot be annotated. The HCPC will approve the education programmes delivering training in exemptions. Approving

those programmes means that education programmes meet the standards that the HCPC sets. Members of the public, employers and others can check that an orthoptist is registered and annotated via the HCPC website, www.hcpc-uk.org.uk or by contacting the HCPC's Registrations Department.

### 17. Why is there an 8 week public consultation on this proposal?

Exemptions are a supply and administration mechanism and are not a form of prescribing. A qualified practitioner is able to supply and administer only from a limited list of medicines within their scope of practice. As there is less professional autonomy than a practitioner using a prescribing mechanism it was recommended by the MHRA that a shortened consultation period was appropriate.

### 18. What happens next?

Following close of the consultation, responses received will be collated and analysed. The CHM and the MHRA will evaluate the responses and make recommendation(s) to Ministers. If the recommendation(s) is/are to amend legislation to allow orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations ( 2012) and Ministers agree to the recommendation(s), MHRA will take forward work to make the relevant amendments.

### 19. When will this legislation come into effect?

Due to the processes involved in achieving the necessary changes to legislation, it is not possible at this stage to give a definitive timeframe for these changes and for the subsequent training programmes to be developed. However, the first intake of orthoptists on an exemptions training programme would not be before 2016. We will however keep people informed of the progress of the project as it develops.

### 20. Why was an equality analysis not undertaken for this public consultation?

The general equality duty that is set out in the Equality Act (2010) requires public authorities, in the exercise of their functions, to have due regard for the need to:

- Eliminate unlawful discrimination, harassment, victimisation and other conduct prohibited by the Act;
- Advance equality of opportunity between people who share a protected characteristic and those who do not;
- Foster good relations between people who share a protected characteristic and those who do not.

Under the previous public sector equality duties (for race, disability and gender), public bodies sometimes took unnecessary, inappropriate, disproportionate or counter-productive action in the name of equality. The new Equality Duty aims to reverse the overly-bureaucratic and burdensome approach often used under the previous duties, so that the focus is on performance, not process. Therefore it does not impose a legal requirement to conduct an Equality Impact Assessment, nor is there any practical need to conduct one. Compliance with the Equality Duty involves consciously thinking about the three aims of the Equality Duty as part of the process of decision-making and has been an integral part of the development of this consultation and all supporting documentation. The responses to the equality questions posed in this consultation will feed into the ongoing equality analysis that will in turn inform the policy decisions made.

# 10 Glossary

| | |
|---|---|
| Allied Health Professions | A group of professionals who work in health and social care. They prevent disease, diagnose, treat and rehabilitate patients of all ages and all specialities. Together with a range of technical and support staff they deliver patient care, rehabilitation, treatment, diagnostics and health improvement to restore and maintain physical, sensory, psychological, cognitive and social functions. Dietitians, orthoptists, paramedics and radiographers are Allied Health Professionals. |
| British and Irish Orthoptic Society (BIOS) | The professional body dedicated to representing UK and Republic of Ireland orthoptists. |
| Commissioners: | NHS commissioners and Clinical Commissioning Groups (CCGs) are responsible for planning and purchasing healthcare services for their local population. They work with local providers to organise and deliver healthcare services which better meet the needs of patients. |
| Commission on Human Medicines (CHM) | A committee that advises ministers on the safety, efficacy and quality of medicinal products. |
| Department of Health (DH) England | The Department of Health helps people to live better for longer. We lead, shape and fund health and care in England, making sure people have the support, care and treatment they need, with the compassion, respect and dignity they deserve. |
| Department of Health, Social Services and Public Safety (Northern Ireland) | It is the Department's mission to improve the health and social well-being of the people of Northern Ireland. It endeavours to do so by:<br>• Leading a major programme of cross-government action to improve the health and well-being of the population and reduce health inequalities. This includes interventions involving health promotion and education to encourage people to adopt activities, behaviours and attitudes which lead to better health and well-being. The aim is a population which is much more engaged in ensuring its own health and well-being; and<br>• Ensuring the provision of appropriate health and social care services, both in clinical settings such as hospitals and GPs' surgeries, and in the community through nursing, social work and other professional services. |
| Exemptions | Exemptions within the Human Medicines Regulations (2012) permit certain medicines to be sold, supplied and/or administered to patients by identified health professional groups. |

| | |
|---|---|
| Health and Care Professions Council (HCPC) | The regulator of 16 different health and care professions including the allied health professions. It maintains a register of health and care professionals and is responsible for setting the standards of training, conduct, and competence for these professionals. |
| Human Medicines Regulations (2012) | The Human Medicines Regulations (2012) governs the control of medicines for human and veterinary use, which includes the manufacture and supply of medicines. |
| Independent prescriber | An independent prescriber is a practitioner responsible and accountable for the assessment of patients with undiagnosed and diagnosed conditions and for decisions about the clinical management, including the prescription of medicines. |
| Licensed medicines | A medicine must be granted a licence by the appropriate body before it can be widely used in the UK. A licence indicates all the proper checks have been carried out and the product works for the purpose it is intended for. |
| Medicines and Healthcare Products Regulatory Agency (MHRA) | MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. The MHRA is an executive agency of the Department of Health. |
| Orthoptist | Orthoptists are one of the allied health professionals with a core role of diagnosing and treating squints, double vision and reduced vision. |
| Patient Group Direction (PGD) | A written instruction for the supply and/or administration of a licensed medicine (or medicines) in an identified clinical situation, where the patient may not be individually identified before presenting for treatment. Each PGD must be signed by both a doctor and pharmacist; and approved by the organisation in which it is to be used. |
| Patient Specific Direction (PSD) | A prescribers (usually written) instruction for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis. |
| Scottish Government Health and Social Care Directorate | Aims to help people sustain and improve their health, especially in disadvantaged communities, ensuring better, local and faster access to healthcare. The Directorate also allocates resources and sets the strategic direction for NHS Scotland and is responsible for the development and implementation of health and social care policy. |

| | |
|---|---|
| Supplementary prescribing | A voluntary prescribing partnership between the independent prescriber (a doctor) and the supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement. |
| Welsh Department of Health and Social Services | Is the devolved Government for Wales - working to help improve the lives of people in Wales and make the nation a better place in which to live and work. The aim is to promote, protect and improve the health and well-being of everyone in Wales by delivering high quality health and social care services, including funding NHS Wales and setting a strategic framework for adult and children's social care services. Where there are inequalities in health, work takes place across Government to tackle the social, economic and environmental influences that affect health and well-being. |