NHS England

Summary of the responses to the public consultation on proposals to allow orthoptists to sell, supply & administer medicines under exemptions within Human Medicines Regulations 2012 across the United Kingdom

Prepared by the Allied Health Professions Medicines Project Team

NHS England – February 2016

Publications Gateway Reference:	04803
Document Purpose	Report
Document Name	Summary of the responses to the public consultation on proposals to allow orthoptists to sell, supply & administer medicines under exemptions within Human Medicines Regulations 2012 across the United Kingdom
Author	AHP Medicines Project Team
Publication Date	26 February 2016
Target Audience	CCG Clinical Leaders, CCG Accountable Officers, Foundation Trust CEs , Medical Directors, Directors of Nursing, NHS England Regional Directors, Allied Health Professionals, GPs, Directors of Children's Services, NHS Trust CEs
Additional Circulation List	
Description	Summary of the responses to the public consultation on proposals to allow orthoptists to sell, supply and administer medicines under exemptions within Human Medicines Regulations 2012 across the United Kingdom. The public consultation took place between February and April 2015.
Cross Reference	Consultation on proposals to allow orthoptists to sell, supply and administer medicines under exemptions within Human Medicines Regulations 2012
Superseded Docs (if applicable)	N/A
Action Required	N/A
Timing / Deadlines (if applicable)	**N/A**
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1 Executive Summary

The purpose of this document is to provide a summary of the responses given to the public consultation on proposals to allow orthoptists to sell supply and administer medicines under exemptions.

It is recommended that this summary is read alongside the full consultation document, which is available on the NHS England website here.

This summary document can also be requested in alternative formats, such as easy read, large print and audio. Please contact: enquiries.ahp@nhs.net

1.1 Outline of proposal

In February 2015, NHS England consulted on proposals to amend medicines legislation to allow orthoptists to be able to train to sell, supply and administer medicines under exemptions.

Exemptions within the Human Medicines Regulations 2012 are defined in law allowing specific listed medicines to be sold, supplied and/or administered to patients by a specific health professional group without the need for another appropriate prescribing or supply/administration mechanism. It is important to recognise that exemptions are a supply and administration mechanism and are NOT a prescribing mechanism.

The proposal relates to orthoptists within the United Kingdom (UK) who meet the specific entrance criteria to gain access to an approved training programme. Upon successful completion of an approved training programme, an orthoptist would then gain annotation on the Health and Care Professions Council (HCPC) register as being qualified to use exemptions within the Human Medicines Regulations 2012.

NHS England proposed that in the course of their professional practice, orthoptists annotated on the HCPC register to use exemptions would be able to sell (when they are providing care in the private sector), supply or administer any eye drops or ointments containing any of the following substances for any condition within their scope of practice and competence. All of the substances listed overleaf are for topical administration only:

Exemptions list

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

In addition, non-prescription medicines (medicines which are available over the counter from a shop or pharmacy) for supply and administration in the course of professional practice (e.g. phenylephrine 2.5%, fluorescein and ocular lubricants).

Sodium cromoglicate has been removed from the list of Prescription Only Medicines (POMs) as it is available as a Pharmacy (P) medicine. Chloramphenicol remains on the exemptions list as it is only available in P form for patients over the age of 2 years: orthoptists frequently care for children under the age of 2.

1.2 Background to the consultation

- In 1999, recommendations from *The Review of Prescribing, Supply and Administration of Medicines*[1] informed policy to improve: patient care, choice and access; patient safety; the use of health professionals skills; and flexible team working.

- In 2009, the *AHP Prescribing and Medicines Supply Mechanisms Scoping Project*[2] found 'a strong case in support of the use of exemptions' by orthoptists.

- In October 2013, the NHS England AHP Medicines Project Team was established to take this work forwards under the Chief Allied Health Professions Officer.

- A case of need for the introduction of the use of exemptions by orthoptists was developed based on improving quality of care for patients, whilst also improving efficiency of service delivery and value for money.

[1] Department of Health (1999) *Review of Prescribing, Supply & Administration of Medicines.* London, DH. http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4077151

[2] 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

- Approval of the case of need was received from NHS England's Medical and Nursing Directorate's Senior Management Teams in May 2014 and from the Department of Health Non-Medical Prescribing Board in July 2014.

- In August 2014, ministerial approval was received to commence preparation for a public consultation with agreement from the devolved administrations in Scotland, Wales and Northern Ireland.

1.3 Public consultation

NHS England led an 8 week public consultation between 26 February and 24 April 2015 on the proposal to allow Orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations 2012.

The UK wide consultation was developed in collaboration 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.

Notification of the consultation was published on the NHS England website with links provided on the professional body website. Responses could be submitted via an online portal (Citizen Space), by email or in hard copy.

1.4 Summary of responses to the consultation

204 responses were received in total. 198 responses were received via the online portal and 6 were received in hard copy.

57 responses were received from organisations and 143 from individuals.

4 responses did not state whether they were responding as an individual or on behalf of an organisation.

There were 32 responses from Scotland, 4 responses from Wales, 17 responses from Northern Ireland, 139 responses from England and 12 responses that did not state which country they were responding from.

Of those:

Exemptions

- 100% (57) of organisations, 93% (133) of individuals and 100% (4) of unidentified respondents supported the proposal.

List of medicines

- 91% (52) of organisations, 78% (112) of individuals and 75% (3) of unidentified respondents agreed with the proposed list of medicines.

Inclusion of antibiotics

- 96% (55) of organisations, 74% (106) of individuals and 50% (2) of unidentified respondents agreed that chloramphenicol and fusidic acid should be included on the proposed list of medicines.

1.5 Next steps

The results of the public consultation were presented to the Commission on Human Medicines (CHM) for their consideration in September 2015 and they published their recommendations in November 2015, a summary of which can be accessed here.

The CHM recommendations were submitted to Ministers for approval and an agreement to extend Human Medicines Regulations legislation to include exemptions for the sale, supply and/or administration of specified medicines by orthoptists was announced in February 2016.

MHRA are taking forward the necessary amendments to UK-wide medicines legislation and the NHS Regulations will be amended accordingly.

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

The HCPC have developed draft standards in relation to the use of exemptions by orthoptists. These standards will enable education providers to consistently interpret and apply the requirements. These standards will go to public consultation in early 2016.

If 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 the summer of 2017, with orthoptists practising with exemptions by the autumn of 2017.

2 Background

2.1 General information

Orthoptists are statutory registered AHPs and 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. There are currently 1,380 (as of November 2015) orthoptists registered with the HCPC.

Orthoptists diagnose and manage amblyopia (the reduction of vision in one or both eyes) and treat patients with ocular imbalance (squint) and double vision. Orthoptists are 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 assessment of the patient's field of vision.

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.

2.2 Current supply and administration of medicines by orthoptists

Under current medicines legislation 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 Specific Direction (PSD)** is a prescriber's (usually written) instruction that enables an orthoptist to supply or administer a medicine to a named patient.
- **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 by a specified health care professional.

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.

2.3 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 Bachelor of Science or Bachelor of Medical Sciences in Orthoptics. Currently, these qualifications are offered at three universities within the UK.

Orthoptists are regulated by the HCPC. Orthoptists must be registered with the HCPC to practise in the UK and must meet the standards set 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 can take action to protect the public where orthoptists do not meet the necessary standards, including removing them from practice where appropriate.

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 continuing professional development and work only within their scope of practice and competence. An orthoptist's scope of practice is the area 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 that 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 use medicines outside of their scope of practice and competence, the HCPC could take action against them to protect the public.

Draft Practice Guidance for Orthoptists for the Supply and Administration of Medicines via Exemptions was developed by the British and Irish Orthoptic Society (BIOS) and presented for consideration as part of the public consultation. The practice guidance has now been updated in line with comments received during the consultation process and the final version published on the BIOS website which can be accessed here.

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.

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.

2.4 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 practise. The portfolio declares how CPD has contributed to both the quality of their practise and service delivery, whilst providing evidence as to how their CPD has benefited the service.

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.

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.

Orthoptic departments and individual orthoptists often use the HCPC and BIOS frameworks to support their CPD requirements and to structure annual appraisal processes.

2.5 Education programmes for orthoptists using exemptions

The HCPC have developed draft standards for the use of exemptions by orthoptists. This will ensure consistency to enable education providers to interpret and apply the requirements. The HCPC will consult on these standards in 2016.

The HCPC will approve and monitor the educational programmes that will deliver training to ensure that the programmes meet the necessary standards. An orthoptist would only be able to use exemptions if they met the entry requirements to access training and then successfully complete an educational programme which will lead to their entry on the HCPC Register being '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.

An *Outline Curriculum Framework for Education Programmes to Prepare Orthoptists to Use Exemptions* has been developed by BIOS and is available to access on the BIOS website here.

The framework outlines the requirements for annotation on the HCPC register as qualified to use exemptions and is aimed at education providers intending to develop education programmes for orthoptists to use exemptions and individuals interested in undertaking an education programme.

2.6 Eligibility criteria for orthoptists wishing to train to use exemptions

Not all orthoptists will 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 practicing 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 the 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.
- In England and Wales, provide evidence of a Disclosure and Barring Service (DBS) or in Northern Ireland, an Access NI check within the last three years or in Scotland, be a current member of the Protection of Vulnerable Groups (PVG) scheme.

*If self-employed, must be able to demonstrate an identified need for prescribing and that all appropriate governance arrangements are in place.

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.

2.7 How exemptions would be used in orthoptic practice

Orthoptists must only work within their scope of practice and competence (the diagnosis and management of disorders of binocular vision, vision development and eye health) and the same will apply to the use of exemptions. If an orthoptist extends their role to a new area of practice they must be competent in that area before they can use exemptions.

The development of the use of exemptions by orthoptists is part of a drive to make it easier for patients to have access to the medicines they need, reduce inequalities (within access to medicines), improve the patient experience and make better use of orthoptists' skills within the multi-disciplinary team at 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.

The examples provided below describe the way in which orthoptist use the current supply and administration mechanisms available to them and how their practice will change once changes to legislation have been laid to enable orthoptist to sell, supply and administer medicines under exemptions from the Human Medicines Regulations 2012. An orthoptists will need to gain entry to and successfully complete a HCPC approved training programme in order to have their HCPC registration annotated before they can use exemptions within their practice.

For example**:**

Timely 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, regardless of where or who they are working with. They therefore support patients to access the right medicines, at the right time, in the right place and without unnecessary delay.

Managing amblyopia

When children with reduced vision in one eye (amblyopia) require treatment, the orthoptist usually offers patching as the first option. Pharmaceutical blurring of the better eye has been shown to be as effective[3], though is not offered as a first line treatment by many orthoptists due to a lack of access to this medicine through the use of PGDs. With the use of exemptions, patients can be offered atropine routinely as a 1st line treatment option and will benefit from timely access to the right choice of treatment.

Inequality of care

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 allow orthoptists to have access to a range of medicines, thereby ensuring patients continue to have access to the type of medicines they require even when there is unavailability of a product.

2.8 Benefits of exemptions

While the use of PGDs and PSDs has helped to improve the effectiveness of care for some patients, there is potential for orthoptists to contribute far greater benefits when practising with exemptions, including:

- Timely access to medicines in order to ensure maximum benefit for patients.
- Improved safety by reducing delays in care.
- Improved patient experience by reducing the number of additional appointments needed to access medicines.
- A reduction in healthcare inequalities by removing local variations in the provision of care by orthoptists which occurs through the use of PGDs.
- Increased choice by allowing orthoptists to access the treatment of choice for patients who do not fit the rigid criteria of the PGD, e.g. pharmaceutical occlusion as an alternative to conventional patching for amblyopia.
- Enabling new roles and ways of working.

[3] 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

- Creating clear lines of responsibility and accountability for the supply and administration of medicines.
- Making better use of the skills of orthoptists within the multi-disciplinary team at a time where there is an increasing demand on ophthalmology services.

2.9 Antimicrobial Stewardship

All healthcare workers including orthoptists 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.

NICE Guideline NG15 Antimicrobial stewardship: systems and processes for effective antimicrobial medicine use[4] provides detailed recommendations for both organisations (commissioners and providers) and individual prescribers and other health and social care practitioners, regarding the use of antibiotics and antimicrobial stewardship. Like all healthcare providers orthoptists and their employing organisations will be required to consider antimicrobial stewardship and follow national and local policies and guidelines 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 into account local antibiotic resistance patterns. The local policy should also cover diagnosis and treatment of common infections and prophylaxis of infection. Orthoptists will also be required to follow *Antimicrobial Prescribing and Stewardship Competencies*[5].

[4] National Institute for Health and Care Excellence (NICE) (2015) *Guideline NG15: Antimicrobial stewardship: systems and processes for effective antimicrobial medicines use* https://www.nice.org.uk/guidance/ng15/resources/antimicrobial-stewardship-systems-and-processes-for-effective-antimicrobial-medicine-use-1837273110469

[5] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies* https://www.gov.uk/government/publications/antimicrobial-prescribing-and-stewardship-competencies

3 Consultation Process

3.1 General

The changes to medicines legislation will apply throughout the United Kingdom and therefore the consultation was 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.

The UK-wide consultation was held between 26 February and 24 April 2015.

3.2 Communications

Invitations to respond to the public consultation were sent to the Chief Executives of NHS Trusts, Clinical Commissioning Groups, Royal Colleges, Healthcare Regulators and other national professional organisations. Medical Directors, Directors of Public Health, Directors of Nursing, Directors of Adult Social Services, and NHS England Regional and Area Directors also formed part of the target audience.

Organisations and groups with an interest were contacted including third sector organisations, patient groups, arm's length bodies and NHS networks.

NHS England also undertook engagement meetings with a number of Royal Colleges and Professional Bodies during the consultation period to support them responding to the consultation. Notification of the consultation was published on the NHS England website with links provided on the BIOS website.

3.3 Methods

Responses to the consultation could be submitted in one of the following ways:

1. By completing the online consultation on the NHS England Consultation hub website.
2. By downloading a PDF copy of the reply form from the NHS England Consultations webpage and emailing the completed form to the AHP consultation mailbox.
3. By printing the reply from or requesting a hard copy to complete and return by post.

The consultation documents were also available in alternative formats, such as easy read, Welsh language, large print, and audio upon request.

3.4 Patient and public engagement

During the consultation period public and patient engagement events were held in England, Scotland and Northern Ireland (this latter event was held after the closing date for the consultation on the use of exemptions by orthoptists).

The events were an opportunity for patients, carers and the public to develop their understanding of the four proposals being taken forwards as part of the AHP Medicines Project and which included:

- Independent prescribing by radiographers
- Independent prescribing by paramedics
- Supplementary prescribing by dietitians
- Use of exemptions by orthoptists

Attendees had an opportunity to take part in small group discussions and ask questions in order to seek clarity on the proposals.

An event was not held in Wales as it was decided by the Welsh Government that the communications strategy they already had in place was sufficient and therefore did not warrant further engagement.

3.5 Equality and health inequalities

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it.

- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

The extension of medicines mechanisms aims to improve patients' access to the medicines they need in a variety of settings. It may specifically benefit and reduce barriers in access to medicines for different equality groups included in, but not restricted to those included in the Equality Act 2010:

- Age
- Disability
- Gender reassignment
- Marriage and civil partnership
- Pregnancy and maternity
- Race
- Religion or belief
- Sex
- Sexual orientation

Additionally, other specific groups should be considered when developing policy, including: children and young people, travellers, immigrants, students, the homeless and offenders.

The issue of equality and health inequalities were addressed two-fold:

1. As part of the patient and public engagement exercises (see section 3.4) a health inequalities table-top discussion was held to gain feedback from participants and consider the impact of proposed changes on all of the above protected characteristics and specific groups.

2. Two questions were posed as part of the public consultation to identify any impact on the protected characteristics and specific groups (see section 3.6).

It can be concluded from the responses to the consultation that changes to legislation to allow orthoptists to use exemptions would have a positive impact on many of the protected characteristics and groups but no negative impact on any characteristic or group.

Any further work in respect of monitoring and evaluation will also take into account our *Equality and Health Inequalities legal duties*[6].

[6] NHS England (2015) *Equality and Health Inequalities legal duties.* NHS England, London https://www.england.nhs.uk/about/gov/equality-hub/legal-duties/

3.6 Consultation questions

Respondents to the consultation were required to give their name and email address, as well as 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 'Draft Practice Guidance for orthoptists for the supply and administration of medicines via 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?

4 Consultation Responses

The consultation received 204 responses in total. 198 responses were received via the online portal (Citizen Space) and 6 responses were received in hard copy.

Responses were received from all four countries of the UK as outlined in table 1 below.

Responses by Country	Number of responses received
England	139
Scotland	32
Northern Ireland	17
Wales	4
Not answered	12
Total responses	**204**

Table 1: Breakdown of consultation response by country

As outlined in table 2 below, 57 organisations responded to the consultation and 143 responses were received from individuals, of which 17 were from patients, carers or members of the public and 126 responded as a health care professional including: doctors, nurses, pharmacists and allied health professionals.

Responses by individuals	**143**
Healthcare professionals	126
Public, carers/patients	17
Responses by organisations	**57**
Did not state if responding as an individual or organisation	**4**
Total responses	**204**

Table 2: Breakdown of respondents

The responses were categorised into 6 groups as outlined in table 3 below; groups 1 to 5 comprise all of the organisational responses, sorted by organisation type, while the 6th group includes all individual responses.

Group 1	Organisations and Networks; Professional Bodies and Royal Colleges; Regulators; Government & Arm's Length Bodies
Group 2	Health Professional Organisations, Professional Bodies and Advisory Groups
Group 3	Educational Bodies/Establishments
Group 4	Commissioning, Commercial and Non-Commercial Organisations; Service Providers; Independent Sector and Trade Associations
Group 5	Patient and Public Representatives; Charitable and Voluntary Associations
Group 6	Responses from Individuals

Table 3: Organisational Groups

Appendix B lists all organisational responses to questions 1, 2 and 3, as these questions were directly related to the proposal with the remainder of the questions relating to the supporting documents and the impact of the proposal on equality and health inequalities.

4.1 Summary of responses by question

4.1.1 Responses to question 1

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?*

Response options:
- Yes
- No

100% (57) of organisations and 93% (133) of individuals supported the proposal.

The breakdown (number and percentage) by group can be seen in table 4 overleaf.

	Organisations												Individuals		Other*	
	Group 1		Group 2		Group 3		Group 4		Group 5		All Organisations		Group 6			
Option		%		%		%		%		%		%		%		%
Yes	14	100	21	100	7	100	9	100	6	100	57	100	133	93	4	100
No	0	0	0	0	0	0	0	0	0	0	0	0	9	6	0	0
Not answered	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0
Total	14	100	21	100	7	100	9	100	6	100	57	100	143	100	4	100

*did not say whether they were responding on behalf of an organisation or as an individual

Table 4: Breakdown by group for responses to question 1

121 comments were received in total for question one. These include six comments from individuals who did not support the proposal and 44 positive comments that were received on behalf of organisations.

The themes identified in responses to this question from both organisations and individuals included: the positive impact of the proposal on patient experience, by reducing the number of appointments needed to access medicines; the potential to facilitate service re-design (e.g. through the development of new community-based services); and the potential to improve patient safety through timely treatment.

The comments below are a selection from those who supported the proposal:

> *This will improve patient care by optimising timely and appropriate access to specific medicines for patients under orthoptic care.*
> **Royal College of Ophthalmologists Paediatric Sub-Committee**

> *There is no standard process regarding the provision of such processes currently. However, where available, the provision of such services has enabled good collaboration between ophthalmologists and orthoptists and the delivery of good care for patients. Therefore we are supportive of amendments to legislation to allow orthoptists to sell, supply and administer particular medicines.* **British Medical Association (BMA) GP Committee**

> *The UKOPG supports this proposal to give orthoptists the opportunity to use certain drugs in their professional practice as is the case for a range of other healthcare professionals.* **UK Ophthalmic Pharmacy Group (UKOPG)**

> *This will support orthoptists in their work in using products that they are already familiar with, increasing efficiency and access.* **Scottish Directors of Pharmacy**

We are strongly supportive of the proposals to allow orthoptists to sell and administer medicines under the relevant exemptions. The evidence from other professions where changes to legislation relating to medicines have been introduced is that it facilitated patients timely access to appropriate medicines, particularly compared to relatively inflexible mechanisms such as patient group directives and patient specific directives. This improved access has multiple benefits. Centrally, it improves patients' experience of care and should improve care outcomes through speeding up appropriate treatment. It will also support the current aspirations of the health service across the UK to increase the responsiveness of services to patient needs, making the most of the existing orthoptist workforce to create more efficient and effective treatment pathways. **Council of Deans of Health**

A minority of comments were neutral or negative and included reference to the need to ensure appropriate training is in place or questioned the need for access to medicines by orthoptists. A selection of these comments are presented below.

Orthoptists almost never work independently from doctors, or outside the NHS - there is no need for them to have exemptions when there are plenty of people around them to support the necessary use of such medicines in their work. **Optometrist**

Patient safety comes first and the high demands on the NHS should not be used as an excuse to lower the standards of care… **Doctor**

4.1.2 Responses to question 2

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?*

The proposed list of medicines can be viewed in Appendix A.

Response options:

- Yes
- No
- Partly

91 % (52) of organisations and 78% (112) of individuals agreed with the proposed list of medicines.

The breakdown (number and percentage) by group can be seen in table 5 overleaf.

	Organisations												Individuals		Other*	
	Group 1		Group 2		Group 3		Group 4		Group 5		All Organisations		Group 6			
Option		%		%		%		%		%		%		%		%
Yes	11	79	20	95	7	100	9	100	5	83	52	91	112	78	3	75
No	0	0	0	0	0	0	0	0	0	0	0	0	9	6	0	0
Partly	3	21	0	0	0	0	0	0	1	17	4	7	20	15	1	25
Not answered	0	0	1	5	0	0	0	0	0	0	1	2	2	1	0	0
Total	14	100	21	100	7	100	9	100	6	100	57	100	143	100	4	100

*did not say whether they were responding on behalf of an organisation or as an individual

Table 5: Breakdown by group for responses to question 2

There were 84 comments in total to this question, the majority of which were from respondents who agreed with the current list without any proposed changes. There were 24 comments from respondents who partly agreed with the list and there were four comments from individuals who did not agree.

The themes identified in the responses to this question, from both organisations and individuals included the proposed list of drugs being safe and widely used in routine practise by orthoptists, although reference was also made to the need for robust training to be in place for orthoptists wishing to use exemptions.

Comments from respondents who **agreed** with the proposed list included:

> *The range of medicines covers the typical conditions expected; there are no contentious medicines listed.* **Guild of Healthcare Pharmacists**

> *We would agree. Long-term medicines (such as glaucoma treatments) do not fit the criteria of exemptions and in the future it may be possible for orthoptists to apply for independent prescribing rights which would cover long-term treatment options.* **Allied Health Professions Federation (AHPF)**

> *The use of these medications will allow for more effective and timely diagnosis and treatment of most patients falling within the scope of orthoptic practice. For example, childhood amblyopia may be treated with atropine occlusion therapy from first presentation because additional steps in the care pathway can be avoided.* **All Wales Orthoptic Advisory Committee**

> *Supports streamlining of patient pathways, reduces delays to patients, supports innovative practice.* **Nottingham University Hospital**

> *It has clearly been assessed and presented as suitable for purpose.* **Podiatrist**

Yes I think the range is suitable and very necessary for orthoptists. I can see this helping a great deal in clinic. **Orthoptist**

Comments from respondents who **partly agreed** with the proposed list include:

The list contains all the relevant medicines that an orthoptist should be able to administer without the need for a doctor's directive or instruction. However, there are certain items, e.g. Topical local anaesthetic where there should be no need to sell and supply, only administer. There definitely needs to be appropriate training and checks which are ongoing vs one-off to help ensure these medications are supplied and administered correctly. **Royal College of Ophthalmologists**

It appears that some of the medicines in the list should be used only after a specialist has made a diagnosis. There is concern that there may be delayed diagnosis or misdiagnosis by allowing orthoptists to prescribe in certain conditions. We would therefore recommend a list of conditions that orthoptists can safely prescribe in to avoid the production of delays in diagnosis or misdiagnosis. **British Medical Association (BMA) GP Committee**

Effective treatment of anterior uveitis is already delayed through misdiagnosis as conjunctivitis by GPs when patients present with red eye. **Olivis's Vision -Charitable Association**

I have no problem with the list of medicines identified which are all either eye drops or ointments but I do wonder whether this list will future-proof the profession in terms of their growing roles in practice. This is in particular with regards to the management of Glaucoma. **Nurse**

All organisations responded 'Yes' or 'Partly' to this question. Comments from individuals responding 'no' to this question (n=9) were brief but suggested that the use of medicines was outside the orthoptists' scope of practice.

4.1.3 Responses to question 3

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?*

Response options:

- Yes
- No
- Partly

96% (55) of organisations and 74% (106) of individuals agreed that chloramphenicol and fusidic acid should be included on the proposed list of medicines.

The breakdown (number and percentage) by group can be seen in table 6 below.

	Organisations												Individuals		Other*	
	Group 1		Group 2		Group 3		Group 4		Group 5		All Organisations		Group 6			
Option		%		%		%		%		%		%		%		%
Yes	13	93	21	100	7	100	9	100	5	83	55	96	106	74	2	50
No	1	7	0	0	0	0	0	0	0	0	1	2	23	16	1	25
Partly	0	0	0	0	0	0	0	0	1	17	1	2	13	9	1	25
Not answered	0	0	0	0	0	0	0	0	0	0	0	0	1	1	0	0
Total	14	100	21	100	7	100	9	100	6	100	57	100	143	100	4	100

*did not say whether they were responding on behalf of an organisation or as an individual

Table 6: Breakdown by group for responses to question 3

In total, 97 comments were received to this question, the majority of which were from individuals. Of the 58 individual comments received there were only 12 comments that were not supportive of the proposal.

The themes identified in the responses to this question included the benefits of timely treatment of infection, the importance of antimicrobial stewardship, and the current availability of chloramphenicol over the counter.

Comments from respondents who **agreed** with the inclusion of antibiotics on the proposed list included:

> *Where there may be a documented or suspected allergy to one of these topical antibiotics, an alternative is necessary to avoid delays in treatment.*
> **Royal College of Ophthalmologists**

Orthoptists regularly see and assess young children with minor bacterial external eye infections. Appropriate training/assessment of competencies will ensure the necessary diagnostic skills have been gained and thus to determine which cases can receive topical antibiotics (under exemptions) and which require referral to a medical practitioner. **Royal College of Ophthalmologists Paediatric Sub-Committee**

We support the proposal to include these two antibiotics in the list because we believe this will support patient care by enabling patients to receive the care and medicines they need from appropriately trained orthoptists. We support the requirement for orthoptists to consider antimicrobial stewardship and to follow local policies for antibiotic use. **Royal Pharmaceutical Society**

We would agree. Many children presenting for orthoptic treatment also have infection and orthoptists supplying antibiotics would remove the need for further ophthalmologist/GP appointments and reduce delay to treatment. **Allied Health Professions Federation (AHPF)**

The two antibiotics are long standing treatments with well-established safety profiles. **Guild of Healthcare Pharmacists**

Orthoptists in the North West NHS organisations are already linked in with medicines governance structures within those organisations to devise patient group directions etc. These governance arrangements include antimicrobial stewardship infrastructure such as antimicrobial formularies. Orthoptists are conscious of the considerations involved in the use of these antimicrobials, further information can be made available to them through training etc. and is included in the proposed curriculum of education programmes. **Health Education North West**

Children frequently present at orthoptic review appointments with a 'sticky eye', this will provide patients with improved access to these medications avoiding further costly appointments with their GP. **University of Sheffield**

Patients can be treated by the orthoptist for minor eye infections without needing to see ophthalmologist. **Orthoptist**

These are standard drugs used both for prevention of infection after surgery and treatment of conjunctivitis. They are extensively used by GPs as well. A small proportion of individuals have allergy to Chloramphenicol and they would need to be aware of this and recognise it when it occurs. **Doctor**

Comments from respondents who **partly agreed** with the inclusion of antibiotics on the proposed list included:

> *However, strict guidance should be in place that specifically excludes contact lens wearers who should be referred on for medical or optometric assessment. Contact lenses are the biggest single risk factor for microbial keratitis and the potential for misdiagnosis of Acanthamoeba and severe bacterial infection that do not respond to chloramphenicol or fusidic acid is devastating. In many cases, initiation of antibiotic treatment precludes subsequent microbiological investigation.* **Optometrist**

> *If eyes are infected probably needs a medical opinion and the patient can get chloramphenicol from a pharmacist (if age 2 years).* **Doctor**

> *Orthoptists must show competency in ability to differentially diagnose conditions that require above antibiotics.* **Orthoptist**

> *As long as used appropriately I think this would be fine, obviously as long as the orthoptist understands not to use them unless clinically needed and appropriate.* **Member of the public**

> *Providing there is constant monitoring and training of those administering the drugs.* **Patient**

Comments from respondents who answered **no** to the inclusion of antibiotics on the proposed list included:

> *Use of antibiotics should be restricted to when essential. Supporting information states that patients, especially children, often present with eye infections. How often? Where is the evidence? Acute bacterial conjunctivitis is usually a self-limiting disorder and can, if necessary be treated with a P medicine. Chloramphenicol eye drops 0.5% and 1% eye ointment (supporting information only refers to eye ointment) are available as P medicines for the treatment of acute bacterial conjunctivitis in patients > 2 years. So why do they need the POM version? Optometrists are only allowed to supply in an emergency. Why should orthoptists be different? Suggest consistency needed here.* **UK Ophthalmic Pharmacy Group**

> *Orthoptists do not have the knowledge or experience to diagnose and treat red eye and make a differential diagnosis of infection, uveitis, keratitis, etc.* **Doctor**

> *The role of an orthoptist is not to be treating ocular infection. Inappropriate use of antibiotics is leading to increasing drug resistance and loss of ability to treat infection.* **Doctor**

4.1.4 Responses to question 4

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?*

In total, 39 comments were received, 19 of which were on behalf of organisations. The themes identified in response to this question from both organisations and individuals included the potential to improve patient outcomes and experience, through enhanced access to treatment and the ability to streamline care pathways.

> *In my position as Chair of the Paediatric Sub-Committee of the RCOphth, I believe this will significantly enhance care and modernise/streamline orthoptic care pathways for patients.* **Royal College of Ophthalmologists Paediatric Sub-Committee**

> *We believe it should go forward but are concerned about how the clinical governance and professional development arrangements will work for orthoptists who are self-employed or who become self-employed at a later date. If it is the employer's responsibility to ensure adequate skills, safety and appropriate environments are in place for orthoptists using exemptions, how are these checks and balances to be replicated for self-employed orthoptists? How will this be regulated?* **College of Optometrists**

> *Orthoptists deliver a range of services within hospital eye care and within the community, they are autonomous practitioners, delivering a range of diagnostic and therapeutic services. Orthoptists access to these medicines will benefit patients and will improve efficiency and quality of care pathways.* **University of Sheffield**

4.1.5 Responses to question 5

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?*

15 comments in total were received in response to this question, 6 of which were on behalf of organisations. The themes identified in response to this question included the need to ensure training is robust and appropriate, and that training courses are accessible.

It is very important that appropriate training is universally available to all orthoptists who wish to undertake this activity so as not to create a 2 tier service. The document suggests that responsibility for appropriate training and the clinical governance should be with the employing Trust. However, there should also be equal onus on the orthoptist to practice within his/her realm of competence. In addition, much like for doctors, professional indemnity (e.g. by NHSLA) needs to be in place to protect patients and orthoptists. For the small proportion of orthoptists who work in the independent sector, this is even more important. **Royal College of Ophthalmologists**

The examination of the eye structure and function is not part of routine training or clinical practice for orthoptists and requires in-depth training and experience to appropriately use and administer medicines for the eye. Use of diagnostic medicines would be appropriate however therapeutic medicines should be used only by those professions with the necessary skills, training and experience. **Optometrist**

The case for there being a need for orthoptists to undertake treatment of eye disease is not clear. For orthoptists working in the hospital environment, there should be adequate opportunities to seek support from other health care professionals (including optometrists). For the independent orthoptist, perhaps even working alone in private practice, no clear case is provided as to why there is a need to access the exempted PoMs as opposed to providing their patients with appropriate information on where to source the appropriate antibiotics or anti-inflammatory drugs from a pharmacy. **Professor - teaching orthoptists, optometrists and dispensers**

4.1.6 Responses to question 6

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

194 responses were received to this question. 80% (155) of responses agreed, 13% (25) of responses only partly agreed, 7% (14) of responses disagreed, and 10 respondents did not answer this question. 53 comments in total were received, of which 16 comments were on behalf of organisations.

The themes identified in response to this question included examples of how the proposal could save NHS resources by: reducing demand for additional appointments; reduced medical time required to sign prescriptions; and greater opportunity for orthoptists to spend their time more effectively with patients.

Comments from respondents who agreed that the Consultation Stage Impact Assessment gave a realistic indication of the likely costs, benefits and risks of the proposal included:

> *Yes, there will be a cost and a patient experience benefit due to time saved in not having to: 1) obtain PGDs, i.e. 30 hours per year @ staff who are at Band 7/8, which can be used in clinical contact; 2) interrupt the ophthalmologist for 5 minutes for each patient episode; 3) prolong the patients anxiety in anticipation for receiving the drops whilst a prescription is obtained.* **British & Irish Orthoptic Society (BIOS)**

> *A realistic indication of the likely benefits and risks is given. Unable to comment on the costs.* **University of Sheffield**

> *The impact assessment has identified all of the potential benefits and risks, although costs are more difficult to accurately assess. Orthoptists are a small profession but one which has the potential to grow in the future, particularly if their skill set provides them with flexibility in application. Therefore, the potential costs and benefits will be dependent on the extent of growth in both current roles and of the profession in the future.* **Nurse**

Comments from respondents who only partly agreed that the Consultation Stage Impact Assessment gave a realistic indication of the likely costs, benefits and risks of the proposal included:

> *We have some reservations about this as it is hard to assess what the uptake may be prior to the program being rolled out and so the predicted costs may not reflect the true cost*. **British Medical Association (BMA) GP Committee**

> *There is likely to be a financial and a time cost to training.* **The Royal College of Ophthalmologists**

> *Statement relating to time spent on PGDs by hospital pharmacists (10 minutes per PGD) is a gross underestimate. Hospital pharmacy staff play a major role in the development of PGDs and are involved at many stages of their use…* **UK Ophthalmic Pharmacy Group**

> *The potential cost benefit has possibly been overes*timated. **Orthoptist**

Comments from respondents who disagreed that the Consultation Stage Impact Assessment gave a realistic indication of the likely costs, benefits and risks of the proposal included:

> *The risk inherent in contact lens primary care management and in the use of atropine is ignored.* **Optometrist**

4.1.7 Responses to question 7

7) *Do you have any comments on the proposed practice guidance for orthoptists supplying and administering medicines under exemptions within the Human Medicines Regulations 2012?*

In total, 67 comments were received. Of these, 38 were responses on behalf of organisations. The majority of comments were in support of the practice guidance with no additional changes suggested.

Comments received that expressed support for the draft practice guidance document included:

NICE is pleased to see the Single competency framework for all prescribers acknowledged in the proposed practice guidance. The framework was developed by the National Prescribing Centre (NPC) which is now the NICE Medicines and Prescribing Centre. NICE is working with NHS England and Health Education England to work with professional and regulatory bodies to update the framework. **National Institute for Health and Care Excellence (NICE)**

The guidance is comprehensive and a helpful resource for orthoptists supplying and administering medicines under exemptions. We note that a new set of standards for the use of exemptions will be developed by the HCPC and will comment on these when they are available. **Council of Deans of Health**

This document will be invaluable in supporting orthoptists in their practice. The content and format of the document broadly follows the existing guidance that is in place for physiotherapists and podiatrists. This supports the view that medicines use is a professional activity to which the same practice guidance standards should broadly apply across all professions. **Chartered Society of Physiotherapy**

The proposed practice guidance looks appropriate. **University of Sheffield**

A comprehensive document which demonstrates the significant detail that has gone into the safety and needs of proposed exemption practice. **Orthoptist**

It clearly sets out how orthoptists, who are trained to hold exemption rights, will behave and work independently within their scope of practice to ensure patient care and safety. **Member of the public**

Comments received in relation to specific suggestions for improvements covered the need for regular review of the guidance, with training updated annually; further explanation of the extent and limitation of orthoptic practice; and more emphasis on regulation and governance in the document. Additional reference was made to the need for all professions to meet the same standards.

All comments received have been taken into consideration and appropriate amendments have been made in the development of the final practice guidance which can be accessed here.

Comments received which expressed the desire to see amendments made to the draft practice guidance document included:

> *Only that it is important for orthoptists not to work in silos but to continue to work in teams and obtain feedback once this exemption occurs.* **Royal College of Ophthalmologists**

> *We have a slight concern with the statement "An orthoptist 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". Whilst we accept this is 'guidance' and not therefore mandatory, we feel that orthoptists should follow the guidance unless the evidence base evolves.* **Guild of Healthcare Pharmacists**

> *We believe the Practice Guidance is reasonable but suggest it is reviewed on a regular basis, as with all professions.* **Allied Health Professions Federation (AHPF)**

> *In many places it refers to "The patient", whereas in many cases it will be the patient's parent that is the relevant person.* **Doctor**

4.1.8 Responses to question 8

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

In total, 59 comments were received, 34 of which were comments received on behalf of organisations. There were 30 comments agreeing with the content of the draft outline curriculum framework with no further changes suggested. There were 20 comments that suggested changes or raised questions including how the content included clinical skills training. The issue of how funding and backfill for training courses would be organised was also raised.

Comments received that expressed support for the draft outline curriculum framework document included:

> *NICE is pleased to see the Single competency framework for all prescribers acknowledged in the draft outline curriculum. The curriculum will need to align with any update to the competency framework.* **National Institute for Health and Care Excellence (NICE)**

> *A thorough and well-constructed document.* **Paediatric Sub-Committee Royal College of Ophthalmologists**

> *We support the ambition to see education to allow use of the proposed exemptions to be integrated into pre-registration education in due course*. **Council of Deans of Health**

> *The curriculum framework appears to include all considerations needed for this programme.* **Health Education North West**

> *The draft outline covers all aspects of training required to prepare Orthoptists to use exemptions.* **University of Sheffield**

> *I think the proposed education is appropriate. Pharmacology is already taught at undergraduate level and a combination of work based learning and theoretical education should ensure that Orthoptic practitioners are safe and knowledgeable.* **Orthoptist**

Comments received that recommended amendments be made to the draft outline curriculum framework document included:

> *There is a need to ensure the programme adequately prepares orthoptists to use exemptions and we are concerned that this will not be feasible during a 12 week programme*. **British Medical Association GP Committee**

> *Patient counselling does not have sufficient emphasis, e.g. atropine is a very toxic drug…* **UK Ophthalmic Pharmacy Group**

> *Why should anyone have to demonstrate support from their employer? Obviously it is nice to have this, but, what if either an orthoptist is self-employed, or even if they do not have support from their employer, I do not see that this should necessarily exclude them.* ***Doctor***

> *The specifics of the training are not clear in terms of clinical skills to enable a full response.* **Optometrist**

All the above comments have been taken into consideration and appropriate amendments have been made in the development of the final outline curriculum framework which can be accessed here.

4.1.9 Responses to question 9

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?

In total, 60 comments were received in response to this question, of which 25 comments were made on behalf of organisations and 35 made by individuals. All responses indicated that there would be a positive impact on people, including those with learning disabilities, physical disabilities, older patients, children (with and without disabilities), and people of all ethnicities with darker irises.

> *Many people with congenital eye conditions are unable to drive, the proposal would reduce the number of times a person needs to visit the hospital using public transport or taxis' etc*. **Nystagmus Network**

> *In essence, this proposal should facilitate timely access to appropriate treatment. It should therefore provide positive benefits to any patient group typically disadvantaged by inequalities focused on access to healthcare, whether from disability, ethnicity or age.* **Council of Deans of Health**

> *Positive benefits for those who find it difficult to access healthcare as this may ultimately reduce clinic attendances. Children, young people and adults with Learning disabilities and adults with stroke are more often seen by Orthoptists than any other groups of eye professionals. These groups of patients already trust the orthoptist as a professional and administering and supplying medicines will provide a seamless package of care for them.* **BIOS Northern Region**

> *Potentially patients with disabilities following stroke and brain injury will receive treatment for eye conditions sooner meaning better quality of life and rehabilitation.* **Orthoptist**

> *The proposal will have a positive impact on all patients. It will provide better access to care through fewer appointments or a single appointment and less disruption to education, parents, and carers.* **Orthoptist**

> *This should have only a positive impact for all patient groups and allow an equitable service.* **Doctor**

> *This should make children's eye care more equal.* **Patient**

4.1.10 Responses to question 10

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?

In total, 66 comments were received in response to this question. Of these, 27 comments were made on behalf of organisations with the majority of responses stating that there would be a positive impact on the identified groups.

Responses indicated that changes would have a positive impact on children and groups who are part of a transient population and therefore are more likely to attend only once (for example, traveller communities, students, hard to reach groups) because fewer appointments were needed. One respondent said the proposal would have a positive impact in rural communities for the same reason.

A selection of comments received are presented below:

> *This proposal will certainly have a positive impact on some of these groups. Travellers and offenders are groups who will frequently present on one occasion only. Therefore all opportunities need to be maximised to treat this group "on the spot". These patient groups will have the advantage of being able to complete an episode of care without need to re-attend.* **All Wales Orthoptic Advisory Committee and Welsh Branch British and Irish Orthoptic Society**

> *Children should be able to access care quicker, e.g. with penalisation treatment for amblyopia or for bacterial conjunctivitis with the topical antibiotics which normally needs a medic to prescribe.* **Royal College of Ophthalmologists**

> *The proposal will have a positive impact on care for children. This is due to the opportunity to complete treatment in a single appointment. Examples are improved access to atropine as first line treatment for amblyopia therapy, which recent evidence suggests should be used more frequently, and from antibiotic treatment when required.* **University of Sheffield**

> *Patients within these groups can often be erratic in attendance. Exemptions will make it easier for patients to access the medicines that they need, when they need them, reduce the number of appointments required and ultimately result in faster access to treatment for many. This proposal should have positive impact for these patient groups.* **NHS Education for Scotland**

Positive for many groups; carers, those from rural areas, school age, also cost issues for all; savings to avoid travelling, parking at hospitals, anxiety and time. **Orthoptist**

It will have a positive impact on children, parents and families caring for children with complex disability. **Doctor**

5 Next Steps

The results of the public consultation were presented to the Commission on Human Medicines (CHM) for their consideration in September 2015, and they published their recommendations in November 2015, a summary of which can be accessed here.

The CHM recommendations were submitted to Ministers for approval and an agreement to extend Human Medicines Regulations legislation to include exemptions for the sale, supply and/or administration of specified medicines by orthoptists was announced in February 2016.

MHRA are taking forward the necessary amendments to UK-wide medicines legislation and the NHS Regulations will be amended accordingly.

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

The HCPC have developed draft standards in relation to the use of exemptions by orthoptists. These standards will ensure education providers consistently interpret and apply the requirements. These standards will go to public consultation in early 2016.

If 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 the summer of 2017, with orthoptists practicing with exemptions by the autumn of 2017.

6 Appendices

6.1 Appendix A: Proposed list of medicines

Provided it is in the course of their professional practise, 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 practise and competence:

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

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

Sodium cromoglicate has been removed from the list of Prescription Only Medicines (POMs) as it available as a Pharmacy (P) medicine. Chloramphenicol remains on the exemptions list as it is only available in P form for patients over the age of 2 years: orthoptists frequently care for children under the age of 2.

6.2 Appendix B: List of organisational responses by group

Appendix B lists all organisational responses to questions 1, 2 and 3, as these questions were directly related to the proposal with the remainder of the questions relating to the supporting documents and the impact of the proposal on equality and health inequalities.

Q1. Should amendments be made to allow orthoptists to sell, supply and administer particular medicines under exemptions within the Human Medicines Regulations 2012?

- Yes
- No

There were two responses on behalf of the same organisation in group 2 and group 5. Both responses are reported.

Group 1: National organisations and networks; professional bodies and Royal Colleges; regulators; government & Arm's Length Bodies

Organisation	Response
Association of British Dispensing Opticians	Yes
Association of Optometrists	Yes
British Medical Association GP Committee	Yes
College of Optometrists	Yes
Federation of Ophthalmic and Dispensing Opticians	Yes
Guild of Healthcare Pharmacists	Yes
Health and Care Professions Council	Yes
Local Optical Committee Support Unit	Yes
NICE	Yes
Paediatric Sub-Committee Royal College of Ophthalmologists	Yes
Royal Pharmaceutical Society	Yes
Scottish Directors of Pharmacy	Yes
The Royal College of Ophthalmologists	Yes
UK Ophthalmic Pharmacy Group	Yes

Group 2: Allied health professional organisations, professional bodies and advisory groups

Organisation	Response
All Wales Orthoptic Advisory Committee	Yes
BIOS - midland area	Yes
BIOS Informatics Special Interest Group	Yes
BIOS private practice SIG	Yes
BIOS Professional Development Committee	Yes
BIOS Scottish Network	Yes
BIOS SEN SIG	Yes
BIOS	Yes
British & Irish Orthoptic Society	Yes
British & Irish Orthoptic Society Low Vision Special Interest Group	Yes
British & Irish Orthoptic Society Specific Learning Difficulties Special Interest Group	Yes
Chartered Society of Physiotherapy	Yes
College of Paramedics	Yes
College of Podiatry (response 1)	Yes
College of Podiatry (response 2)	Yes
Glaucoma and Retinal Disease Special Interest Group BIOS	Yes
Northern Region - British and Irish Orthoptic Society 297 members collective response	Yes
Royal College of Speech and Language therapists	Yes
The Allied Health Professions Federation	Yes
The College of Occupational Therapists	Yes
Vision Screening Special Interest Group, British & Irish Orthoptic Society	Yes

Group 3: Educational bodies/establishments

Organisation	Response
Council of Deans for Health	Yes
Health Education North West	Yes
NHS Education for Scotland	Yes
Robert Gordon University Aberdeen	Yes
University of Liverpool	Yes
University of Sheffield	Yes
University of Sheffield Student	Yes

Group 4: Commissioning, commercial and non-commercial organisations; service providers; independent sector and trade associations

Organisation	Response
County Durham and Darlington Foundation Trust	Yes
Dorset NHS CCG	Yes
Hillingdon Hospital	Yes
Imperial College Healthcare NHS trust	Yes
NHS Highland	Yes
Nottingham University Hospital	Yes
South Tees Hospitals NHS Foundation Trust	Yes
The Royal Free NHS Foundation Hospital	Yes
University Hospitals Birmingham NHS Trust	Yes

Group 5: Patient and public representatives; charitable and voluntary associations

Organisation	Response
Berkshire County Blind Society	Yes
Healthwatch Bolton	Yes
Nystagmus Network	Yes
Olivia's Vision	Yes
Thomas Pocklington Trust (response 1)	Yes
Thomas Pocklington Trust (response 2)	Yes

Q2: *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?*

- Yes
- No
- Partly

Group 1: National organisations and networks; professional bodies and Royal Colleges; regulators; government & Arm's Length Bodies

Organisation	Response
Association of British Dispensing Opticians	Yes
Association of Optometrists	Yes
British Medical Association GP Committee	Partly
College of Optometrists	Yes
Federation of Ophthalmic and Dispensing Opticians	Yes
Guild of Healthcare Pharmacists	Yes
Health and Care Professions Council	Yes
Local Optical Committee Support Unit	Yes
NICE	Yes

Paediatric Sub-Committee Royal College of Ophthalmologists	Yes
Royal Pharmaceutical Society	Yes
Scottish Directors of Pharmacy	Yes
The Royal College of Ophthalmologists	Partly
UK Ophthalmic Pharmacy Group	Partly

Group 2: Allied health professional organisations, professional bodies and advisory groups

Organisation	Response
All Wales Orthoptic Advisory Committee	Yes
BIOS - midland area	Yes
BIOS Informatics Special Interest Group	Yes
BIOS private practice SIG	Yes
BIOS Professional Development Committee	Yes
BIOS Scottish Network	Yes
BIOS SEN SIG	Yes
BIOS	Yes
British & Irish Orthoptic Society	Yes
British & Irish orthoptic Society Low Vision Special Interest Group	Yes
British and Irish Orthoptic Society Specific Learning Difficulties Special Interest Group	Yes
Chartered Society of Physiotherapy	Yes
College of Paramedics	Yes
College of Podiatry (response 1)	Yes
College of Podiatry (response 2)	Yes
Glaucoma and Retinal Disease Special Interest Group BIOS	Yes
Northern Region - British and Irish Orthoptic Society 297 members collective response	Yes
Royal College of Speech and Language therapists	Not Answered

The Allied Health Professions Federation	Yes
The College of Occupational Therapists	Yes
Vision Screening Special Interest Group, British & Irish Orthoptic Society	Yes

Group 3: Educational bodies/establishments

Organisation	Response
Council of Deans for Health	Yes
Health Education North West	Yes
NHS Education for Scotland	Yes
Robert Gordon University Aberdeen	Yes
University of Liverpool	Yes
University of Sheffield	Yes
University of Sheffield Student	Yes

Group 4: Commissioning, commercial and non-commercial organisations; service providers; independent sector and trade associations

Organisation	Response
County Durham and Darlington Foundation Trust	Yes
Dorset NHS CCG	Yes
Hillingdon Hospital	Yes
Imperial College healthcare NHS trust	Yes
NHS Highland	Yes
Nottingham University Hospital	Yes
South Tees Hospitals NHS Foundation Trust	Yes
The Royal Free NHS Foundation Hospital	Yes
University Hospitals Birmingham NHS Trust	Yes

Group 5: Patient and public representatives; charitable and voluntary associations

Organisation	Response
Berkshire County Blind Society	Yes
Healthwatch Bolton	Yes
Nystagmus Network	Yes
Olivia's Vision	Partly
Thomas Pocklington Trust (response 1)	Yes
Thomas Pocklington Trust (response 2)	Yes

Q3: 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?

- Yes
- No
- Partly

Group 1: National organisations and networks; professional bodies and Royal Colleges; regulators; government & Arm's Length Bodies

Organisation	Response
Association of British Dispensing Opticians	Yes
Association of Optometrists	Yes
British Medical Association GP Committee	Yes
College of Optometrists	Yes
Federation of Ophthalmic and Dispensing Opticians	Yes
Guild of Healthcare Pharmacists	Yes
Health and Care Professions Council	Yes
Local Optical Committee Support Unit	Yes
NICE	Yes

Paediatric Sub-Committee Royal College of Ophthalmologists	Yes
Royal Pharmaceutical Society	Yes
Scottish Directors of Pharmacy	Yes
The Royal College of Ophthalmologists	Yes
UK Ophthalmic Pharmacy Group	No

Group 2: Allied health professional organisations, professional bodies and advisory groups

Organisation	Response
All Wales Orthoptic Advisory Committee	Yes
BIOS - midland area	Yes
BIOS Informatics Special Interest Group	Yes
BIOS private practice SIG	Yes
BIOS Professional Development Committee	Yes
BIOS Scottish Network	Yes
BIOS SEN SIG	Yes
BIOS	Yes
British & Irish Orthoptic Society	Yes
British & Irish Orthoptic Society Low Vision Special Interest Group	Yes
British and Irish Orthoptic Society Specific Learning Difficulties Special Interest Group	Yes
Chartered Society of Physiotherapy	Yes
College of Paramedics	Yes
College of Podiatry (response 1)	Yes
College of Podiatry (response 2)	Yes
Glaucoma and Retinal Disease Special Interest Group BIOS	Yes
Northern Region - British and Irish Orthoptic Society 297 members collective response	Yes
Royal College of Speech and Language Therapists	Yes

The Allied Health Professions Federation	Yes
The College of Occupational Therapists	Yes
Vision Screening Special Interest Group, British & Irish Orthoptic Society	Yes

Group 3: Educational bodies/establishments

Organisation	Response
Council of Deans for Health	Yes
Health Education North West	Yes
NHS Education for Scotland	Yes
Robert Gordon University Aberdeen	Yes
University of Liverpool	Yes
University of Sheffield	Yes
University of Sheffield Student	Yes

Group 4: Commissioning, commercial and non-commercial organisations; service providers; independent sector and trade associations

Organisation	Response
County Durham and Darlington Foundation Trust	Yes
Dorset NHS CCG	Yes
Hillingdon Hospital	Yes
Imperial College Healthcare NHS Trust	Yes
NHS Highland	Yes
Nottingham University Hospital	Yes
South Tees Hospitals NHS Foundation Trust	Yes
The Royal Free NHS Foundation Hospital	Yes
University Hospitals Birmingham NHS Trust	Yes

Group 5: Patient and public representatives; charitable and voluntary associations

Organisation	Response
Berkshire County Blind Society	Yes
Healthwatch Bolton	Yes
Nystagmus Network	Yes
Olivia's Vision	Partly
Thomas Pocklington Trust (response 1)	Yes
Thomas Pocklington Trust (response 2)	Yes

6.3 Appendix C: Glossary of terms

Allied Health Professions (AHPs)	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.
British and Irish Orthoptic Society (BIOS)	The professional body dedicated to representing UK and Republic of Ireland orthoptists.
Commission on Human Medicines (CHM)	A committee that advises ministers on the safety, efficacy and quality of medicinal products.
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: • 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 • 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.

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.
Pharmacy (P) medicine	Pharmacy medicines are available from a pharmacy without a prescription, but under the supervision of a pharmacist.
Prescription Only Medicine (POM)	Prescription Only Medicines are medicines that require a prescription, usually from a GP, but may be prescribed by a dentist, nurse, pharmacist, midwife or other healthcare professional
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.
Topical Administration	A topical medication is a medication that is applied to a particular place on or in the body, as opposed to systemically.
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.