



Patient and public summary for:

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

The full consultation document is available on the NHS England consultation hub website [here](#).

Prepared by the Allied Health Professions
Medicines Project Team

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Patient and public summary for: Consultation to allow orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012) across the United Kingdom

This summary document has been produced primarily for patients and members of the public to accompany the *Consultation to allow orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012) across the United Kingdom* which can be accessed on the NHS England consultation hub website [here](#). This summary document has been considerably condensed and **does not** contain all the detailed information on this proposal such as patient safety, training and education.

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

Contents	4
1 Summary	5
2 Introduction	5
3 About the consultation.....	6
4 Background and context	6
4.1 The role of orthoptists	6
4.2 Current use of medicines by orthoptists	6
4.3 Which orthoptists would be able to sell, supply and administer particular medicines directly to patients under exemptions?.....	7
4.4 Arrangements for introducing the use of exemptions by orthoptists.....	7
4.5 Benefits of the use of exemptions by orthoptists	7
5 Proposals	7
5.1 Introduction of exemptions by orthoptists.....	7
5.2 Antibiotics.....	8
5.3 Additional information.....	8
5.4 Supporting documents: impact assessment, practice guidance and education curriculum framework	9
5.4.1 Impact assessment	9
5.4.2 Practice guidance	9
5.4.3 Education curriculum framework.....	10
5.5 Equality	10
6 How to respond to this consultation	11
7 Next steps.....	11
8 Glossary	12

1 Summary

The NHS is consulting on proposals to enable orthoptists who have undertaken the appropriate training to be able to sell, supply and administer particular medicines to their patients via exemptions from the Human Medicines Regulations (2012).

Orthoptists are allied health professionals with a core role of diagnosing and treating squints, double vision and reduced vision in patients ranging from premature babies to older people.

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.

There are a number of questions on this proposal, and everyone is welcome to respond to the consultation.

The consultation will run for 8 weeks and closes on **24 April 2015**

This document is a summary of the full consultation document which is available on the NHS England consultation hub website [here](#).

A glossary of terms is included at the end of this document.

2 Introduction

In recent years, the NHS has enabled a wider range of health professionals to prescribe or supply and/or administer medicines to patients. This makes it easier for patients to get access to the medicines that they need in a timely manner so they gain maximum benefit.

The NHS is now consulting on proposals for four separate groups of allied health professionals across the United Kingdom to have wider access to medicines for their patients. These proposals include:

- Independent prescribing by radiographers
- Independent prescribing by paramedics
- Supplementary prescribing by dietitians
- Use of exemptions within Human Medicines Regulations (2012) by orthoptists

These proposed changes will allow these healthcare professionals to better use their skills to care for their patients. This will mean that patients will be able to access medicines as part of their treatment at the most appropriate time and place.

This document covers the consultation on proposals to allow orthoptists across the United Kingdom who have undertaken the necessary training, to be able to sell, supply and administer particular medicines directly to patients under exemptions within the Human Medicines Regulations (2012).

3 About the consultation

This consultation has been prepared by NHS England with support from the British and Irish Orthoptic Society, the Medicines and Healthcare Products Regulatory Agency (MHRA), the Department of Health, 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.

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.

Everyone is welcome to respond to the questions in this consultation as outlined in section 6. This consultation will run for 8 weeks and responses should be sent to arrive no later than: **24 April 2015**.

4 Background and context

4.1 The role of orthoptists

Orthoptists diagnose and manage amblyopia (the reduction of vision in one or both eyes) and treat patients with ocular imbalance (squint) and double vision. They may also work with patients who have brain injuries, diabetes, stroke, retinal disease, glaucoma and children with developmental delay or adults with learning difficulties.

Orthoptists work in a variety of settings across the UK, from community clinics to large hospital settings. They 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.

In response to increasing demand, the role of the orthoptist has developed significantly in recent years, including the introduction of extended roles such as testing for defective focusing in children with squint and reduced vision, glaucoma care and retinal photography.

4.2 Current use of medicines by orthoptists

Under current medicines legislation, orthoptists can already supply and administer medicines to some patients via Patient Group Directions (PGDs) and Patient Specific Directions (PSDs). However, the restrictions attached to the current arrangements can prevent patients getting the medicines they need, when they need them. This limits the range of patients who can benefit.

While the existing arrangements have helped to improve the effectiveness of care for some patients, there is potential for orthoptists to contribute further and achieve far greater benefits if they are able to practice with exemptions.

More detailed information about how orthoptists currently provide patients with medicines can be found in the main consultation document [here](#).

4.3 Which orthoptists would be able to sell, supply and administer particular medicines directly to patients under exemptions?

Not all orthoptists would train to use exemptions. The safety of patients is paramount. Orthoptists wishing to train to use exemptions would need to meet a number of requirements such as working in an environment where there is an identified need for the individual to use their exemptions. For a full list of entry requirements see section 3.6 of the *Consultation on proposals to allow orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012) across the United Kingdom* which can be accessed on the NHS England consultation hub website [here](#).

4.4 Arrangements for introducing the use of exemptions by orthoptists

Once an orthoptist has successfully completed their training for exemptions this will be recorded on their professional Register by the Health and Care Professions Council (HCPC) which is the professional regulator. In the interests of patient safety they will be required to maintain their skills and keep their knowledge up to date.

Orthoptists using exemptions must show they are up to date by undertaking appropriate continuing professional development and demonstrating that they continue to practice both safely and effectively.

4.5 Benefits of the use of exemptions by orthoptists

Benefits of the use of exemptions by orthoptists would include patients being able to get the medicines they need at the right time and in the right place for maximum benefit. This will be more convenient for patients by reducing the number of appointments they need and the number of healthcare professionals they need to see to get the medicines they need.

The use of exemptions by orthoptists will also allow changes to be made to the way services are organised and delivered to better meet the needs of patients. For example, orthoptists would be able to offer a greater choice of treatment for children with reduced vision and so extra appointments with eye doctors would be avoided.

5 Proposals

5.1 Introduction of exemptions by orthoptists

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

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- 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).

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)?

5.2 Antibiotics

Orthoptists are specialists in children's eye care. Patients, especially children, who are being treated by orthoptists often present with eye infections which may need treatment with antibiotics. It is important that orthoptists are able to provide these patients with the medicines they need without delay and therefore two antibiotic medicines (Chloramphenicol and Fusidic acid) have been included on the proposed list of medicines that orthoptists will be able to provide to patients.

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)?

5.3 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?

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

5.4.1 Impact assessment

Impact assessments are part of the policy making process. The purpose of an impact assessment is to consider why changes are necessary, what impact the policy change is likely to have and to highlight the costs, benefits and risks of the change.

The *Consultation Stage Impact Assessment* for the proposal to allow orthoptists to sell, supply and administer medicines under exemptions within the Human Medicines Regulations (2012) is available on the NHS England consultation hub website [here](#) and contains the information about the actual (where available) and estimated costs, benefits and risks of the proposal.

This consultation is an opportunity to gather additional information and evidence to further inform 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?

5.4.2 Practice guidance

The professional body for orthoptists (The British and Irish Orthoptic Society) has developed practice guidance for orthoptists using exemptions which provides information that should underpin the decision-making and actions of orthoptists who are able to use exemptions. The 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 able to use exemptions. An orthoptist using exemptions will be expected to justify any decision to act outside the practice guidance and, in particular, if the orthoptist undertakes an action not recommended by this guidance there must be robust reasons for doing so.

The consultation is an opportunity to gather feedback and comments on the guidance developed 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 7: Do you have any comments on the proposed practice guidance for orthoptists supplying and administering medicines under exemptions?

5.4.3 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. This curriculum framework is aimed at education providers intending to develop education programmes for orthoptists to use exemptions. 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 consultation is an opportunity to gather 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'?

5.5 Equality

Orthoptists have a responsibility to contribute to equality in healthcare by working towards eliminating discrimination and reducing inequalities in care.

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 patients in small community hospitals, and specialist clinics or services, as well as groups in rural and remote locations, and travellers.

Orthoptists using exemptions would be able to provide care in some cases without the need for eye doctors, who would be free to concentrate on more complex cases. The use of exemptions would also reduce inequalities of care by allowing orthoptists to provide patients with the medicines they need regardless of where or who the orthoptist is employed by. Convenience for patients would be improved by reducing the number of appointments needed to access medicines, especially in rural locations where an eye doctor is not always available.

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?

6 How to respond to this consultation

You can respond to this consultation 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

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

The consultation remains open for 8 weeks and responses should be sent to arrive no later than: **24 April 2015**

7 Next steps

Following the close of the consultation, the Commission on Human Medicines (CHM) will be asked to consider the proposals in light of comments received. Subject to the advice from CHM and to agreement by Ministers, the Medicines and Healthcare products Regulatory Agency (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 2016.

8 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 only 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: <ul style="list-style-type: none"> • 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 from medicines legislation permit certain medicines to be sold, supplied and/or administered to patients by identified health professional groups.

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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 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.
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.

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