Practice Guidance for orthoptists for the supply and administration of medicines under exemptions

February 2016

Table of Contents

Foreword		3
Introduction		4
Standards for use of exemptions		5
Scope of Medicines Use by Orthoptists		5
Registration and Professional Indemnity Insurance		6

SECTION 1: GUIDELINES ON THE SUPPLY AND ADMINISTRATION OF MEDICINES UNDER EXEMPTIONS

Practice Guidance 1:	Licence to use exemptions	7
Practice Guidance 2:	Accountability	7
Practice Guidance 3:	Assessment	8
Practice Guidance 4:	Clinical need	9
Practice Guidance 5:	Consent	9
Practice Guidance 6:	Communication	10
Practice Guidance 7:	Record-keeping	11
Practice Guidance 8:	Evidence based use of medicines/use of medicines in the patients best interest	12
Practice Guidance 9:	Delegation	13
Practice Guidance 10:	Supply of medicines on the recommendation of others	13
Practice Guidance 11:	Information given to patients	13
Practice Guidance 12:	Reviewing Medications	14
Practice Guidance 13:	Children	14
Practice Guidance 14:	Mixing of Medicines	14
Practice Guidance 15:	Storage	15
Practice Guidance 16:	Transportation	15
Practice Guidance 17:	Disposal	15
Practice Guidance 18:	Error Reporting	15
Practice Guidance 19:	Reporting unexpected effects and adverse reactions	16
Practice Guidance 20:	Complementary, herbal and homeopathic products	16

SECTION 2: CLINICAL GOVERNANCE

Practice Guidance 21:	Governance Structures	17
Practice Guidance 22:	Clinical Audit	17
Practice Guidance 23:	Supply and Administration Analysis	18
Practice Guidance 24:	Learning from incidents and errors	18
Practice Guidance 25:	Risk Management	18
Practice Guidance 26:	Continuing Professional Development	18
Practice Guidance 27:	Poor Performance	18
Practice Guidance 28:	Links with Pharmaceutical Companies / Conflict of interest	19
Practice Guidance 29:	Gifts and Benefits	19
Practice Guidance 30:	Checking Registrations and Annotations	19
Glossary		20
Appendix		26
Acknowledgements		30

Foreword

I am delighted that this document 'Practice guidance for orthoptists for the supply and administration of medicines under exemptions' has been completed. It recognises that orthoptists are key eye care professionals whose clinical work will benefit from the additional skill of supplying and administering agreed appropriate medications.

The demand on ophthalmology hospital care has expanded exponentially in recent years because of longevity of the population, increasing chronic disease and the development of new successful long-term treatments. Optimising the role of orthoptists, who are trained to diagnose and manage several eye conditions, will help to expand the supply of ophthalmic care both in the primary and secondary care settings. This will be enhanced by the use of exemptions which will be of benefit to the patients under their care.

This document sets out how orthoptists who are trained to hold exemption responsibilities will behave and work independently within their scope of practice to ensure patient care and safety. Further training will be delivered to ensure that the health needs of individuals and groups with eye disease, visual impairment and binocular defects are addressed by this development, which is a positive step for ophthalmic services.

Professor Caroline MacEwen
President, The Royal College of Ophthalmologists

Introduction

This document provides information which should underpin the decision-making and actions of orthoptists who are annotated with the Health and Care Professions Council (HCPC) as having access to exemptions within Human Medicines Regulations 2012 to be able to supply and administer listed prescription only medicines (POMs) and pharmacy (P) medicines.

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. This document provides advice on the behaviours and conduct expected of orthoptists who are annotated on the HCPC register as able to access exemptions. Throughout this document the use of the word 'must' indicates a legal and/or regulatory requirement and describes a mandatory action and/or behaviour. The use of the word 'should' indicates behaviours and/ or actions that would be expected to occur in all normal circumstances. Each section of this guidance carries equal weight and the document is not ordered in any priority.

If an orthoptist accessing exemptions from medicines legislation deviates from the advice given in this document, the clinical judgement for so doing must be carefully recorded. You should comply with this practice guidance, other guidance issued by the British and Irish Orthoptic Society (BIOS) and with any statutory requirements applicable to the use of exemptions in practice. Failure to do so may put your HCPC registration at risk if concerns are raised about your fitness to practice. If a complaint is made against you, an HCPC fitness-to-practice committee may take account of this document and those to which it makes reference. An orthoptist accessing exemptions will be expected to justify any decision to act outside the terms of this 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. This guidance document should be read in conjunction with the HCPC Standards, the BIOS Code of Ethics, and the BIOS Competency Standards and Professional Practice Guidelines.

The advice in this document applies to all sectors of health and social care provision in the United Kingdom where medicines use occurs.

At the current time the supply and administration of medicines under exemptions by orthoptists is not permitted outside of the UK and therefore an orthoptist permitted to use exemptions in the UK cannot perform this activity outside of UK jurisdiction.

Standards for the use of exemptions

The HCPC define the standards of proficiency that are required by orthoptists.

Draft standards for the use of exemptions have been developed by the HCPC and will go to public consultation in early 2016.

The Scope of medicines use by orthoptists

The purpose of exemptions for orthoptists is to support and enhance the delivery of care to patients by expanding the current mechanisms by which orthoptists deliver care. As such, orthoptists will use exemptions to support and enhance the delivery of orthoptic based care that is aimed at addressing health and well-being needs of individuals and groups related to eye disease, visual impairment and binocular defects.

Orthoptists must only work independently within their scope of practice and the same will apply to the use of exemptions. If an orthoptist extends their role to a new area of practice they will need to show they are competent in that area before they can access exemptions within this role.

Orthoptists using exemptions must have sufficient education, training and competence to:

- assess a patient's clinical condition
- undertake a thorough history, including medical history and medication history (including over-the-counter medicines and complementary therapies), and allergy status
- diagnose where necessary
- decide on management of the presenting condition and whether or not to supply or administer medicines under exemptions and/or refer on to another healthcare professional
- identify appropriate products of medication as required
- advise the patient on risks, benefits and outcomes of the medication
- supply or administer medicines with the patient or carer's consent
- monitor the patient's condition, including any response to the medication supplied/administered
- give lifestyle advice as appropriate

Registration and Professional Indemnity Insurance (PII)

Since July 2014 all HCPC registrants have been required to have proof of adequate indemnity to practice in order to maintain their registration. Orthoptists who are members of the BIOS benefit from Professional Indemnity Insurance (PII) as part of their membership. In order for their PII to be in force (subject to the terms of the policy) members must:

- hold current registration with the HCPC
- hold a current appropriate BIOS membership at the time that treatment or advice is given
- be practising lawfully
- be practising within the overall scope of the profession

If orthoptists are to access exemptions they must successfully complete an approved training programme and be annotated on the HCPC register before accessing this mechanism in practice.

Orthoptists who are not members of BIOS will need to ensure they have adequate insurance or other indemnity arrangement in place for their practice.

SECTION 1: Guidelines on supply and administration of medicines under exemptions

This section provides advice and guidance on the supply and administration of medicines through the use of exemptions. Having achieved the competencies for this, orthoptists are expected to follow this advice in their practice.

The advice and guidance provided in this document applies to all settings in which an orthoptist may access exemptions – within the NHS, private practice, prison service, armed forces or any other provision.

The BIOS considers it good practice that, where orthoptists are employed, the employing organisation signs off all protocols and procedures. Where possible orthoptists accessing exemptions should follow organisational level policies and procedures and should only create local department level procedures when no national or organisational policy or procedure is in existence.

Practice Guidance 1: Licence to use exemptions

1.1 You must only use exemptions once you have successfully completed an HCPC approved exemptions programme and been annotated on the HCPC Register as qualified to use exemptions.

1.2 Orthoptists should comply with this and other guidance issued by BIOS, and with any statutory requirements applicable to their use of exemptions. Failure to do so may put their registration at risk.

1.3 You must only use exemptions for identified medicines within your scope of practice and competency.

1.4 You must understand which legal framework you are using to supply and/or administer medicines and understand which medicines you are permitted to supply and/or administer within that framework.

Practice Guidance 2: Accountability

2.1 You are professionally accountable for your decisions regarding the supply and administration of medicines under exemptions, including actions and omissions. You cannot delegate this accountability to any other person nor can any other person accept accountability on your behalf for your actions.

2.2 You must only ever access medicines under exemptions within your level of education, training and competence, acting in accordance with any relevant standards.

2.3 If you move to another area of practice you may need to undertake further training in order to establish your competency to use exemptions in your new clinical speciality.

2.4 Your employer may operate a specific medicines formulary (derived from the specific list of exemptions approved in legislation) and may not allow you to supply and administer medicines outside of this formulary. This restricted formulary would only apply to your practice for that employer.

2.5 You must inform the relevant authorities, such as your employer and/or provider of indemnity insurance, if you have any formal regulatory restrictions which may affect your use of exemptions, for example, if the HCPC has placed any conditions on your practice.

Practice Guidance 3: Assessment

3.1 In order to supply or administer medicines to a patient under exemptions you must satisfy yourself that you have undertaken a full assessment of the patient, including a thorough history and, where possible, accessing a full clinical record including medication and allergy history.

3.2 You should supply or administer medicines to a patient under exemptions only where you have relevant knowledge of the patient's health and medical history commensurate with the medicines decisions you are taking.

3.3 You should ensure you have considered the patient's current medication and any potential interactions with other medicines.

3.4 You should take steps to ensure that the patient is not suffering from any medical condition or receiving any other treatment that would make the use of any medicine unsuitable or dangerous.

3.5 You should ensure you consider the effects of your patient's lifestyle which may affect the safety of the medicines you supply or administer. This will include:
- The effects of smoking, caffeine and alcohol
- The effects of 'recreational' or 'street' drugs or those used to enhance physical or sporting performance
- The effects of over-the-counter medicines including herbal preparations.

3.6 Where necessary you should have the ability to request and/or have access to the results of additional appropriate tests. These tests should be relevant to the presenting condition and/or appropriate to the medicines decisions to be made.

3.7 You should refer to an appropriate prescriber if you do not fully understand the implications of the actions of your medicines use even though you may be able to take a thorough and appropriate history which leads to a diagnosis.

Practice Guidance 4: Clinical Need

4.1 You must only supply or administer medicines when you have assessed the patient and there is a genuine clinical need.

4.2 You should consider the circumstances in which you may decide to withdraw medication, cease to continue or alter the dose of a medication supplied under your exemptions. Patients and/or their legal representatives may also wish to discuss with you withdrawal from medication. Any withdrawal from medicines supplied under exemptions needs to be planned in partnership with the patient/legal representative and anyone involved in their care and take place over an agreed time period.

4.3 You should never supply or administer medicines for your own convenience or simply because a patient demands that you do so.

4.4 You should supply and administer medicines in the patient's best interests and achieve this by reaching an agreement with the patient and/or their legal representative on the use of any proposed medicine. The amount of information you discuss with your patient will vary according to the nature of the patient's condition, the risks and benefits of the medicine and the patient's wishes. In all circumstances this will include the provision of 'sufficient information' to allow the patient to make an informed choice i.e. to give their informed consent. You should aim to:

- Establish the patient's priorities, preferences and concerns
- Discuss other options available to the patient
- Satisfy yourself that you have enough relevant information to make a decision
- Satisfy yourself that the patient understands how to use any medicine supplied.

4.5 You should only supply or administer medicines for patients who are part of your own caseload or under your own care.

Practice Guidance 5: Consent

5.1 You should explain to the patient, or their representative, the role you play in their treatment and undertake appropriate informed consent. You should provide your patient with "sufficient information" relating to the risks, benefits and outcomes of the medicines management you are considering as well as the comparative risks of alternative treatment options to medication that may be considered in order that the patient can give their informed consent to treatment.

5.2 You should be aware of the variety of social, cultural and religious factors that may impact upon the choices your patient makes in agreeing medicines decisions with you.

5.3 You should act in accordance with Department of Health, BIOS and employer guidance on the obtaining and documenting of consent.

5.4 The patient has the right to refuse to accept any medication you propose to supply and/or administer. If they do so you should explain the risks, benefits and outcomes of their decision.

5.5 The patient should be provided with any relevant patient information leaflet (PIL) about the medicine you propose to supply in order to assist them in making an informed decision. Patients with visual impairment should be made aware that they can view this online as an X-PIL or can receive large print, braille or audio versions from the RNIB medicines leaflet line.[1]

Practice Guidance 6: Communication

6.1 You should communicate effectively, using the most appropriate media, with other practitioners involved in the care of the patient. This includes communication across NHS/private practice boundaries where necessary. When sending patient data, it is vital that the data is secure, and that the risk of data loss (including misdirection) is minimised. The Health and Social Care Information Centre have produced a detailed information governance toolkit[2] regarding the safe transfer of patient data which lists the most commonly used methods of communication, along with minimum standards required for safe and secure data transfer. These include:

- Verbal communication: the security and confidentiality of telephone and personal conversations should be considered within the organisation's policy and procedures (e.g. confidentiality code of practice) and included in staff training. Staff should be mindful of the need to maintain security and confidentiality when discussing personal or other sensitive information.
- Portable storage devices (USB Sticks): Use of these devices must only be used following an Information Risk Assessment.
- Postal/Courier Services: Items must be tracked and traceable, and should include arrangements for redirected or undeliverable items.
- Telephone answering machines: This can be used where the recipient is known (i.e. GP practice) and the message will be retrieved in an appropriate manner. Best practice suggests using password protected voicemail wherever possible.
- Internet protocol (IP) phones (including systems such as Skype): These should only be used "point to point" within the secure N3 network. (It is accepted that clinician/patient conversations occur using this method but it is not advised for conversations about patients/clients between healthcare professionals).
- Email: Emails containing patient identifiable data should only be sent using (and receiving) NHSmail email accounts or other approved government email domains.

---

[1] http://www.rnib.org.uk/information-everyday-living-reading-what-read/bills-and-other-paperwork

[2] Department of Health (2010) IG Toolkit Version 8 Information Security Assurance Requirement 322 Detailed Guidance on Secure Transfers (Online) Available at: https://www.igt.hscic.gov.uk/KnowledgeBaseNew/DH_NHS%20IG%20-%20Detailed%20Guidance%20on%20Security%20Measures%20for%20Information%20Transfers.pdf

- Web Based Applications: Movement of patient data within electronic systems must be encrypted and comply with the Confidentiality NHS Code of Practice.
- Short Messaging System (SMS "texting"): SMS should not be used to convey patient data due to the lack of secure transfer methods and retention of sent data.
- Faxing: Patient data which is faxed should be done following the NHS IG Safe Haven principles.

6.2 Supply and administration decisions should be made in partnership with the patient or their legal representative. This will include taking into account the patient's personal views and beliefs and discussing medicine use in relation to these. You should ensure that patients have understood what they have been told and the consequences of decisions that have been agreed.

6.3 Information regarding the supply of medicines must be shared with other health professionals who need to know the information for the benefit of the patient and this will include the patient's GP. You should decide the best methods of sharing this information. Where possible, you should have access to other professionals' prescribing/medicines supply decisions where they impact upon your own decisions. This will include communication across NHS-private practice boundaries where it is necessary to ensure that clinicians have appropriate information to inform their practice.

6.4 You should inform anyone else who may be in a position to prescribe/ supply medicines for that patient of your actions to avoid prescribing/medicines error. This is most likely to be the patient's GP, but you may also include other health and social care professionals. If the patient/legal representative refuses to consent to you sharing such information you should offer an explanation of the risks of not doing so. If the patient continues to refuse to give consent, you should consider which course of action (including not to supply medicines) would be in the best interests of the patient. This must be documented in their records.

6.5 You should know what medication the patient is currently taking including over-the counter and herbal preparations before supplying/administering medicines.

Practice Guidance 7: Record keeping

7.1 This practice guidance relates specifically to the record keeping of your supply and administration of medicines under exemptions. You should refer to other standards and guidance for information relating to clinical record keeping in general.

7.2 Documentation of the supply or administration activity should be recorded in the clinical records at the time of administration or supply. It is not good practice to document medicines supply/administration after the event e.g. at the end of the

clinic session or at the end of the day. Only in exceptional circumstances should documentation be delayed, although in any event the delay should not exceed 24 hours.

7.3 Records must include details of the medicines supplied and/or administered, together with relevant details of the consultation with the patient.

7.4 Your records should show that you have communicated any treatment regimes involving medicines with the primary healthcare record keeper (usually the GP).

Practice Guidance 8: Evidence based use of medicines/use of medicines in the patient's best interests

8.1 You should ensure that the supply and administration of medicines is appropriate, responsible and in the best interests of the patient. You should be aware of the current evidence base supporting the use of any medicines you are supplying or administering.

8.2 You should use national sources of evidence as your primary source of evidence based medicines use. Reference to the evidence base can minimise the risk of adverse drug reactions and ensure the most appropriate medicines are chosen in line with the patient's needs.

8.3 When supplying antibiotics you should consider antimicrobial stewardship and follow local policies for antibiotic use. The local policy is required to be based on national guidance and should be evidence-based, relevant to the local healthcare setting and take into account local antibiotic resistance patterns. They should cover diagnosis and treatment of common infections and prophylaxis of infection. The National Prescribing Centre's (now part of NICE) competencies for all prescribers[3], the 2013 Public Health England / ARHAI Antimicrobial Prescribing and Stewardship Competencies[4] and NICE Guidelines[5] should be used by anyone supplying medicines to help develop their practice at any point in their professional development in relation to the supply of antimicrobials.

8.4 You should ensure your use of exemptions is appropriate and that patients have enough information to make an informed choice. You should consider the following factors to ensure you:

---

[3] National Prescribing Centre provided by NICE (2012). A Single Competency Framework for all Prescribers. London: NICE http://www.npc.co.uk/improving_safety/improving_quality/resources/ single_comp_framework_v2.pdf

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

[5] 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

- Are familiar with the current national sources of evidence for the medicine.
- Are familiar with the current national sources of evidence for the condition you are treating, which may also include current evidence for which medicine groups should be used, or not used, and a hierarchy of medicines use.
- Have taken an appropriate assessment of the patient.
- Have taken into account the patient's preferences and expressed wishes with regard to medicines use.
- Have supplied/administered the appropriate dose for your patient's age and weight.

Practice Guidance 9: Delegation

9.1 You may delegate the administration of a medicine to another healthcare worker or to the patient/their legal representative. You remain accountable for your decision to delegate the task of administration. This includes your assessment that the person is competent to carry out the task and has received sufficient training to carry out your instructions.

9.2 This information should be recorded in the patient record.

Practice Guidance 10: Supply of medicines on the recommendation of others

10.1 You should only use exemptions for patients on your own caseload and under your care. You must not use exemptions for any patients upon whom you have not undertaken an appropriate assessment. You must not use exemptions for a patient unknown to you simply because you are the only orthoptist available with the qualification to use exemptions.

Practice Guidance 11: Information given to patients

11.1 Patients, or their legal representatives, should be given as much information as they require in order for them to make an informed choice with regard to using medicines. You should include:

- Indication for using a diagnostic medicine or diagnosis giving rise to therapeutic need.
- Any known serious or common side effects of the proposed medicine.
- How the medicine works.
- How long to take it for.
- How to stop taking the medicine.

11.2 Information provided should be appropriate to the patient/carer's levels of understanding. Any issues noted related to normal cognition, learning disability or language barrier must be documented and a plan provided to minimise the impact of the issue.

11.3 Where practicable you should support information given to your patients in writing.

11.4 You should tell the patient that their medicines will come with a manufacturer Patient Information Leaflet (PIL) which will give them additional information. In settings where the PIL is not routinely supplied patients can request such information if they wish. Patients with visual impairment should be made aware that they can view this online as an X-PIL or can receive large print, braille or audio versions from the RNIB medicines leaflet line.[6]

Practice Guidance 12: Reviewing Medications

12.1 Where using an exemption to supply a course of treatment you should review the patient regularly.

Practice Guidance 13: Children

13.1 Medicines are potent treatments and using them can present significant risk to patients. This is especially so for children whose responses may differ from adults. You must have relevant education, training and competence in treating children in order to supply and/or administer medicines to them. You should recognise the unique implications of supplying and administering medicines to children and young people. Caution should also be used when supplying or administering medicines for pregnant and lactating women.

13.2 You should make reference to the following documents that address medicine management issues in paediatrics:

- The BNF for children http://www.bnfc.org
- Medicines Standard: National Service Framework for Children, Young People and Maternity Services www.dh.gov.uk (under Policy and Guidance, Health and Social Care topics, Children Services)
- Medicines Standard: National Service Framework for Children, Young People and Maternity Services (Wales) http://www.wales.nhs.uk/sites3/documents/441/englishnsf_amended_final.pdf
- Royal College of Paediatrics and Child Health www.rcpch.ac.uk/publications
- Scottish Executive – The Administration of Medicines in Schools and The Right Medicine: A Strategy for Pharmaceutical care in Scotland http://www.gov.scot/resource/doc/158742/0043086.pdf
- Scottish Intercollegiate Guidelines Network (SIGN) Guidance www.sign.ac.uk
- DHSSPS – Medicines Management Standard https://www.dhsspsni.gov.uk/consultations/medicines-optimisation-quality-framework
- Department of Health (DH) – Every Child Matters (2004) https://www.education.gov.uk/consultations/downloadableDocs/EveryChildMatters.pdf

Practice Guidance 14: Mixing of medicines

14.1 You must not mix medicines. Medicines are rendered unlicensed if they are mixed

[6] http://www.rnib.org.uk/information-everyday-living-reading-what-read/bills-and-other-paperwork

together prior to administration. The law defines mixing as the combination of 2 or more licensed medicines together for the purposes of administering them to a patient.

Practice Guidance 15: Storage

15.1 You should ensure all medicinal products are stored in accordance with the information within the Summary of Product Characteristics or Patient Information Leaflet or information found on the label. Some medicines may require refrigerated storage.

15.2 Medicines can only be stored in “lockable business premises” prior to delivery to the patient. When not in use, medicines should be stored in lockable containers or cabinets or otherwise returned to a Pharmacy department for safe-keeping.

15.3 NHS Staff: You should not store medicines at home unless you have the written permission of your employer to do this which describes the exceptional circumstances that require you to store medicines in your home, and you must have suitable lockable storage facilities in place.

Home-based Private Practice: You must only store medicines in lockable containers that constitute “lockable business premises” which are within the business part of your premises.

15.4 All storage environments must meet the prevailing storage requirements and it is your responsibility to find out what these requirements are. You must ensure correct storage policies are in place and are being adhered to.

Practice Guidance 16: Transportation

16.1 You may transport medicines from the dispensing pharmacy to their place of use.

16.2 You should not leave medicines unattended in your vehicle at any time.

Practice Guidance 17: Disposal

17.1 You must dispose of used, partially used and unused medicines in accordance with current legislation and your local employer policy.

17.2 If there is no local employer policy in place, you must return all medicines to a pharmacist for safe disposal.

Practice Guidance 18: Error Reporting

18.1 If you discover that you have made an error in supply or administration you must take immediate action to prevent potential side effects to the patient and you must report the error as soon as possible according to local protocols.

Practice Guidance 19: Reporting unexpected effects and adverse reactions

19.1 If a patient experiences an adverse reaction to a medication you should record this in the patient notes and notify the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme immediately. Yellow cards are found in the back of the British National Formulary and also online at www.yellowcard.gov.uk

19.2 You should also inform the patient that they can report adverse reactions independently to the Yellow Card Scheme.

19.3 You can also report adverse reactions via the MHRA website at www.mhra.gov.uk and serious incidents for investigation (previously known as Serious Untoward Incidents/ SUIs) to the National Reporting and Learning Service, using National Framework for Reporting and Learning from Serious Incidents Requiring Investigation http://www.nrls.npsa.nhs.uk.

Practice Guidance 20: Complementary, herbal and homeopathic products

20.1 Complementary, herbal and homeopathic products may interact with other medicinal products. You should ensure you obtain, and record, information from the patient as to whether they are using any such products. Where there is evidence that you should do so, you may need to advise that your patient stops using a complementary, herbal or homeopathic product prior to starting taking a conventional medicinal product or undergoing a medical and/or surgical procedure.

20.2 The MHRA regulates other herbal products under the Traditional Herbal Registration (THR) scheme and other homeopathic products under the National Rules Scheme (NRS). Other products may not be subject to regulation of their quality, safety or efficacy. You should only recommend these products if you have suitable education, training and experience to do so.

20.3 The MHRA holds a list of complementary, herbal and homeopathic products that are known to, or may have, interactions with medicinal products and you should be aware of these before recommending that a patient takes a complementary product in addition to, or as a substitute for, any currently supplied medicine. Some herbal preparations are prohibited or restricted in their use in humans due to known toxic and/or harmful effects, and you should not recommend these products to your patients.

SECTION 2: Clinical Governance

Patient safety is of paramount importance within all aspects of supply and administration of medicines. Orthoptists must practise within the law, to a high professional standard, and ensure that they strive continuously to improve the quality of care that they offer to patients. Poor professional performance needs to be identified and rectified at an early stage. The guidance in this section will apply alongside any organisational policies and/or procedures that the organisation may have in place.

Employing authorities both within the NHS and the private/independent sector have clinical governance arrangements in place including protocols, procedures and clinical audits. Orthoptists must ensure that clinical governance systems are appropriate and work within these.

Practice Guidance 21: Governance Structures

21.1 You must follow the governance arrangements that are in place.

Arrangements should be in place for:

- Clear lines of responsibility and accountability for overall quality of clinical care.
- The development of quality improvement programmes, such as clinical audit, supporting evidence based practice, implementation of clinical standards, monitoring of clinical care, access to appropriate CPD programmes.
- Management of risk.
- Procedures to identify and remedy poor performance.

Practice Guidance 22: Clinical audit

22.1 Clinical audit is an important part of clinical governance. You should audit your activities in the use of exemptions.

22.2 You should audit how many of the patients for whom you have supplied and/or administered medicines under exemptions have required medical follow up, and how many have been successfully managed within the orthoptic pathway. You should also audit those patients for whom you took an active decision not to supply and/or administer medicines under exemptions.

22.3 If you are working outside NHS settings, where clinical governance systems may be different or may not be applied in the same way, you must ensure you comply with requirements to demonstrate your competence to practice. For example, you need to be able to demonstrate how you audit your practice, keep up-to-date with current guidance and how you safeguard the patients in your care.

22.4 You should monitor how patients respond to treatment and how many follow up visits are taking place. Systems should be put in place to ensure that patients who do not attend (DNA) for their appointments are followed up (e.g. by telephone, letter, text message or e-mail).

22.5 You should seek your patients' experiences of your use of exemptions where possible.

Practice Guidance 23: Supply and administration analysis

23.1 You should ensure that you have information about national guidelines (e.g. NICE guidelines, NSFs), local guidelines, local agreements and formularies to ensure you make the best decision for your patients.

Practice Guidance 24: Learning from incidents and errors

24.1 You should record all incidents and/or errors with your local reporting systems to facilitate national reporting where required.

24.2 You should review incidents within your local team and/or medicines management committee (or equivalent) to enable learning and where necessary change practice.

Practice Guidance 25: Risk Management

25.1 You should be aware of the appropriate risk management programmes in place relating to exemptions. This should include clinical risk management and patient safety (including the National Reporting and Learning Service http://www.nrls.npsa.nhs.uk), confidentiality and a system for handling errors and complaints.

Practice Guidance 26: Continuing Professional Development

26.1 You must remain up-to-date with appropriate knowledge and skills to enable you to supply and administer medicines competently and safely within your scope of practice.

26.2 You should ensure that your CPD is in line with your current or future practice, including any extended roles you undertake.

26.3 You should record your CPD in a format that easily enables you to demonstrate your fitness to practice as an orthoptist using exemptions.

26.4 You should ensure that you set aside sufficient time to access programmes and resources to meet your CPD needs. This may include Peer Review sessions. You should include reflective learning in your CPD portfolio.

Practice Guidance 27: Poor Performance

27.1 You should be aware of the procedures in place for identifying poor use of exemptions.

Practice Guidance 28: Links with Pharmaceutical Companies / Conflict of interest

28.1 If you have a commercial or financial interest in any pharmaceutical product or company then you should ensure that your interest does not affect your ability to use exemptions in the patient's best interest alone.

28.2 You must not allow your own, or your employer's (if applicable) commercial or financial interests in a pharmaceutical company or product influence the way you advise your patients.

28.3 You must declare any conflict of interest in a 'register of interests' either within your personal portfolio, or within your employers Hospitality Register which should be produced on request for audit purposes.

Practice Guidance 29: Gifts and Benefits

29.1 Your choices for your patients must be based solely on clinical suitability and cost effectiveness, working within any local formulary that you may be obliged to follow.

29.2 The advertising and promotion of medicines is strictly regulated. You must not accept personal gifts that are given to influence your exemptions activity nor must you solicit or accept a gift or inducement to influence your patterns of supply or administration.

29.3 You may accept hospitality for a professional or scientific meeting, but such hospitality should be reasonable in level, and subordinate to, the main purpose of the meeting.

29.4 You may accept awards and/or grants to attend educational events offered by pharmaceutical companies that enable you to undertake CPD relevant to your practice.

29.5 You should follow your employer's policy on receiving gifts and hospitality. If you do not have an employer you should consider whether it is appropriate to accept gifts or hospitality in response to your exemptions activities.

Practice Guidance 30: Checking Registrations and Annotations

30.1 You must provide evidence of your valid registration as an orthoptist with the HCPC to your employer.

30.2 You must only use exemptions in accordance with the annotation awarded to you.

Glossary

Administration	Process by which a medicine is introduced into, or applied onto, the patient's body.
Advice	The act of giving information to service users pertaining to aspects of the condition for which they are seeking intervention. The information given may be an opinion or recommendation relating to suggested future intervention or actions. The information may include guidance to seek the opinion of another health professional. The information is given to the service user to consider, and the service user may choose whether to act on the advice given or not.
Appropriate practitioner	Registered professional defined within medicines legislation as being authorised to issue prescriptions for POM class medicines and/or to receive bulk supplies of POM class medicines.
British and Irish Orthoptic Society (BIOS)	The professional body representing UK and Republic of Ireland orthoptists
British National Formulary	A pharmaceutical reference book containing information and advice on medicines and pharmacology.
Clinical Governance	Quality assured activities which ensure that pre-determined clinical standards that have been set, are maintained by practitioners, and are evident within health care settings.
Commissioner	Person or organisation that requests and/or funds a service or activity.
Competence	The ability of an individual to demonstrate their capability in a certain skill area at a defined level of ability at a set point in time.
Competencies	The component skills that describe and define the actions and activities required in order to demonstrate competence in a skill area.
Controlled drug	A medicine subject to control by the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.

Disposal	The removal and disposal of medicines that are no longer required or are no longer suitable for their intended use and /or the removal of unwanted medicines or waste materials from the clinical site.
Exemption	Specific pieces of law allowing certain listed medicines to be sold/supplied and/or administered to patients by certain health professional groups without the need for another appropriate prescribing or supply/ administration framework.
General Sales List	Products that can be sold without the supervision of a doctor or pharmacist and may be obtained through a variety of outlets.
Guidance	Document containing recommendations for the use of a particular treatment and/or modality; the circumstances when it should be used and the population/patient groups who should receive it. Health professionals have a duty to take guidance fully into account where it is published, but they are not bound by its contents and may deviate from it where there is a clear indication to do so.
Guideline	A wide-ranging recommendation dealing with the management of a disease condition. A guideline document does not impose a duty on a health provider to fund the treatment of the disease condition.
Health and Care Professional Council	The regulator for AHPs, including othoptists
Human Medicines Regulations	The Human Medicines Regulations 2012 governs the control of medicines for human and veterinary use, which includes the manufacture and supply of medicines. The Act defines three categories of medicine: prescription only medicines, which are available only from a pharmacist if prescribed by an appropriate practitioner; pharmacy medicines, available only from a pharmacist but without a prescription; and general sales list medicines which may be bought from any shop without a prescription.

Independent prescriber (IP)	A professional who is registered on the appropriate statutory register for their professional group and (for non-medical staff) against whose name is recorded an annotation signifying that they are qualifed to prescribe medicines as an independent prescriber. They are responsible for the assessment of patients with undiagnosed conditions, and for decisions about the clinical management required including prescribing. They assume full accountability for the prescribing decisions they make. An independent prescriber may be a medical prescriber (doctor/dentist only) or a non-medical independent prescriber (nurse, pharmacist, optometrist, physiotherapist, podiatrist).
Licenced medicine	A medicine with a valid marketing authorisation (product licence) in the UK.
Marketing authorisation (MA)	Formal approval by the MHRA to place a medicinal product on the UK market, formerly known as 'product licence'. Defines the terms, conditions and/ or patient groups that the product may be used for. Use of a medicine outside of the terms of the MA is known as 'off-label' use of the product.
Medical prescriber	A doctor or dentist who can independently prescribe both licensed and unlicensed medicines, and who may instruct another health professional to administer such medicines to patients under the terms of a PSD.
Medicinal product	Defined by MHRA as: "a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; b) Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis" A medicinal product could fall under either point a) or b) above, or both.
Medicine	A substance that claims to, or has the actual function of, treating or preventing disease in humans or animals.

MHRA	The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK.
Mixing	The combining of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient. Mixed medicines are unlicensed.
NHS	National Health Service
National Insitute for Health and Care Excellence	An organisation that provides national guidance and advice to improve health and social care.
Non-medical prescriber (NMP)	A nurse, pharmacist and some allied-health professional groups who are registered on the appropriate statutory register for their professional group, and against whose name is recorded an annotation signifying they are permitted by the relevant law to prescribe medicines as either an independent and/or supplementary prescriber. The limit of their prescribing responsibilities is determined by law and will not be the same for each professional group especially with regard to mixing medicines and controlled drugs.
Orthoptist	A person who is registered on the relevant part of the HCPC register of the Health Professions Order 2001 and entitled to practice using the protected title of 'orthoptist'.
Over-the-counter (OTC)	Description of a medicine that can be supplied without a written prescription from a variety of outlets, including self-selection without supervision, by a patient.
P medicine	Products that can be sold from premises that are under the supervision of a pharmacist but without the need for a written prescription.
Patient Group Direction (PGD)	A written instruction for the supply or administration of a named medicine in a defined clinical situation to groups of patients who may not have been identified before presenting for treatment.

Patient Specific Direction (PSD)	A prescription from a doctor, dentist or other prescriber for a medicine to be administered to a named patient by another health professional. The patient must be individually identified on the PSD. The prescription must be signed and dated by the doctor/ dentist or other prescriber.
PIL	Patient Information Leaflet
POM	Prescription Only Medicine. Such medicines may only be supplied and administered against a valid written 'prescription'.
Prescribe	LEGAL: to request in writing, in the appropriate manner, the supply and administration of a Prescription Only Medicine for use by a named patient. Only 'appropriate practitioners' may prescribe. The Human Medicines Regulations 2012 define the professional groups classed as 'appropriate practitioners'. GENERAL: to authorise in writing, in the appropriate manner, the supply and administration of any medicinal product(s), for use by a named patient. LAY: to advise on the use of a product, especially by an authorised person or to recommend especially as a benefit.
Prescribing	Issuing prescriptions for the medical treatment of a single individual by an 'appropriate practitioner'. A pharmacist is legally required to be involved in the sale and/or supply of the medicine identified within a written prescription. Therefore 'prescribing' is a process by which medicines are supplied to a patient involving at least two separate persons – the prescriber and the pharmacist.

Prescription	LEGAL: a written instruction by an appropriate practitioner for the supply and administration of the medicinal products listed within it. A written tool against which POM's may be supplied. A prescription is issued by an 'appropriate practitioner' under or by virtue of the National Health Service Act 1977 (England) / the National Health Service (Scotland) Act 1978 / the Health and Personal Social Services (Northern Ireland) Order 1972.
Standard	A statement on the level of proficiency expected to be demonstrated by a person professing to hold a certain skill or ability.
Summary of product characteristics	(Previously known as the Data Sheet): Information available for individual licensed medicines, forming an integral part of the marketing authorisation (licence). It provides information for health professionals on how to use the medicinal product safely and effectively.
Supplementary prescriber (SP)	A professional who is registered on the appropriate statutory register for their professional group and against whose name is recorded an annotation signifying that they are qualifed to prescribe medicines as a supplementary prescriber. A person responsible for the continuing care of patients who have been clinically diagnosed by an independent prescriber.
Supply	The activities undertaken, in response to formal orders, when medicines are issued to the place where they will be used, or supplied directly to the patient.
Traditional Herbal Registration (THR) number	MHRA registration scheme for herbal preparations that have been assured for safety, efficacy and quality, i.e. licensing for herbal preparations. Equivalent to a Product Licence for medicines.
Unlicensed medicine	A medicine that does not have a UK marketing authorisation.

APPENDIX
Key Legislation & Terminology

Medicines use in the UK is controlled by the terms of the Human Medicines Regulations 2012 which provide the legislative framework for medicines use in the UK.

Orthoptists must understand the distinctions between the three core frameworks for supply and administration that are available to them.

Supply and Administration Frameworks

Patient Specific Directions (PSD): A Patient Specific Direction is a written instruction from a prescriber for a medicine to be supplied and/or administered to a named patient. It relates to the relationship between the prescriber and another professional. An orthoptist must only administer the medicine in accordance with the instructions that are written by the prescriber. Instructions should be written, although in a genuine life threatening emergency an oral instruction may be given.

Patient Group Directions (PGD): PGDs are not a form of prescribing. A doctor and a pharmacist, in conjunction with the orthoptists who will use the tool, define in writing the named medicines that may be supplied and/or administered to groups of patients who may, or may not, have been individually identified prior to treatment. The PGD must be drawn up in a specific way in order to be legally valid. The orthoptist must supply and administer the medicine in accordance with the instructions that are written within the PGD. PGDs are not valid in all healthcare delivery settings.

Statutory Exemptions: Exemptions are not a form of prescribing. Specific pieces of law allow certain listed medicines to be sold/supplied and/or administered to patients by certain health professional groups without the need for another appropriate prescribing or supply/administration framework.

Categories of Medicines

1. General Sales List Medicines (GSL)
These products can be sold with reasonable safety without the supervision or advice of a doctor or pharmacist, and may be obtained through a variety of outlets. All GSL medicines must hold a valid UK product licence and all the active ingredients must be listed in the product. Regulations restrict the pack sizes and quantities of the medicine that may be sold without supervision. Larger volumes may only be sold under supervision; pharmacy sale medicines (P class) or prescription only medicines (POM Class).

2. Pharmacy sale medicines (P)
These products can be sold with reasonable safety from premises that are under the supervision of a pharmacist but without the need for a written prescription. The products may be available for self-selection by the general public but a pharmacist is aware of the purchase at the point of sale.

Both GSL and P class medicines are known as "over-the-counter" medicines as they can be sold and supplied (in some cases only at certain low volumes) without a written prescription for supply.

3. Prescription Only Medicines (POMs).
The Human Medicines Regulations 2012 define those medicines that must be classed as POMs and include those that:
- Contain listed substances
- Are controlled drugs
- Are for parenteral (i.e. injection) administration (with the exception of insulin)
- Emit radiation
- Come under other listed criteria

POMs may only be sold, supplied and administered in accordance with a written prescription by an appropriate practitioner and dispensed from a registered pharmacy or dispensing doctor's practice.

The Human Medicines Regulations 2012 defines 'appropriate practitioner' for the purposes of issuing written prescriptions:
- Doctor, dentist or vet
- Independent nurse prescriber
- Independent pharmacist prescriber
- Independent optometrist prescriber,
- Independent physiotherapist prescriber
- Independent podiatrist prescriber
- Supplementary prescriber acting under a written Clinical Management Plan (CMP)

4. Controlled Drugs
The Misuse of Drugs Act 1971 controls certain types of drugs that may be liable to misuse and abuse because of their effects on users. Schedule 2 of this Act lists the drugs subject to these specific controls and it categorises the drugs into one of three classes: Class A, Class B and Class C. The term "controlled drug" is used to refer to drugs within these three categories.

The Misuse of Drug Regulations 2001 permits the use of controlled drugs in healthcare and further classifies controlled drugs as one of the five Schedules that reflect the differing levels of control required for use of each category of drug. Controlled drugs are also subject to specific regulations pertaining to the storage and documentation required for their use.

Orthoptist will not have exemptions for any controlled drugs.

MEMBERSHIP OF NHS ENGLAND ALLIED HEALTH PROFESSIONALS MEDICINES PROJECT BOARD

Representative	Organisation
Suzanne Rastrick (Co-Chair)	NHS England
Bruce Warner (Co-Chair)	NHS England
Helen Marriott (Project Lead)	NHS England
Shelagh Morris	NHS England
George Hilton (secretariat)	NHS England
Steven Sims (secretariat)	NHS England
Charlotte Beardmore	Society and College of Radiographers
Jan Beattie	Scottish Government
Rebecca Blessing	Department of Health
Brian Brown	Care Quality Commission
Andy Burman	Allied Health Professions Federation and British Dietetic Assocation
Nicole Casey	Health and Care Professions Council
Bill Davidson	Patient and public representative
Catherine Duggan	Royal Pharmaceutical Society
Gerry Egan	College of Paramedics
Sue Faulding	Health and Social Care Information Centre
Katherine Gough	NHS Clinical Commissioning Group Representative
Linda Hindle	Public Health England
Barry Hunt	College of Paramedics (advisory)
Cathryn James	Association of Ambulance Chief Executives
Rowena McNamara	British and Irish Orthoptic Society
Fleur Nielsen	Council of Deans of Health
Graham Prestwich	Patient and public representative
Anne Ryan	Medicines and Healthcare products Regulatory Agency
Patricia Saunders	Health Education England
Alison Strode	Welsh Government
Hazel Winning	Department of Health, Social Services & Public Safety (Northern Ireland)

MEMBERSHIP OF ALLIED HEALTH PROFESSIONALS MEDICINES PROJECT PRACTICE & EDUCATION WORKING GROUP

Representative	Organisation
Jan Beattie	Scottish Government
Imogen Carter	College of Paramedics
Nicole Casey	The Health and Care Professions Council
Andy Collen	College of Paramedics
Molly Courtenay	University of Surrey
Alison Culkin	St Mark's Hospital, Harrow
David Davis	College of Paramedics
Matt Fitzpatrick	Royal National Orthopaedic Hospital NHS Trust
Jan Flint	Royal Free London NHS Foundation Trust
Christina Freeman	Society and College of Radiographers
Sarah Griffiths	Bristol Haematology and Oncology Centre
Dianne Hogg	East Lancashire Hospitals NHS Trust
Barry Hunt	College of Paramedics
Hannah Kershaw	The Royal Free Hospital
Jancis Kinsman	Bristol Haematology and Oncology Centre
Judy Love	Society and College of Radiographers
Helen Marriott (Project Lead)	NHS England
Nadia Northway	Glasgow Caledonian University
Najia Qureshi	British Dietetic Association
Anne Ryan	Medicines and Healthcare products Regulatory Agency
Claire Saha	British and Irish Orthoptic Society
Steve Savage	Yeovil District Hospital
Steven Sims	NHS England
Alison Strode	Welsh Government
Pip White	Chartered Society of Physiotherapy

ACKNOWLEDGEMENTS

The BIOS acknowledges the following documents which were informative in the creation of this guidance for orthoptists:

Good Practice in Prescribing and Medicines Management for Podiatrists (2013) London. The College of Podiatry and Institute of Chiropodists and Podiatrists.

Practice Guidance for Physiotherapist Supplementary and/or Independent Prescribers in the safe use of medicines (2nd edition) (2013) London. Chartered Society of Physiotherapy.

Guidance for Optometrist Prescribers (2009) London. General Optical Council.

The BIOS acknowledges the guidance and support provided by the individuals from a variety of professions including the NHS England AHP Medicines Project Board and Working Group and especially Christina Freeman, Society and College of Radiographers; Najia Qureshi, British Dietetic Association; Andy Sharman, College of Paramedics and Andy Collen, College of Paramedics

Claire Saha
BIOS Exemptions Project Lead

Published: February 2016
Review Date: February 2020

The British and Irish Orthoptic Society
Salisbury House
Station Road
Cambridge
CB1 2LA
www.orthoptics.org.uk