

***Practice Guidance for Paramedics  
for the Administration of  
Medicines under Exemptions  
within the Human Medicines  
Regulations 2012.***

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## Document Control

This document has been adapted by the College of Paramedics and is based on the original document published by the British & Irish Orthoptic Society (BIOS). References to versions and authors from hereon should also be viewed in consideration of the original document.

Version Control	Comments	Authors
Development of draft versions	Initial adaptation of AHP document to be specific and relevant to paramedic profession	
V0.01	Completion of draft	Imogen Carter
V0.02 – v0.04	Ongoing development of document	Andy Collen
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## Foreword

The College of Paramedics is delighted to have developed this Practice Guidance document on the use of medicines exemptions. Paramedic practice has developed significantly over the last two decades and the use of medicines exemptions has provided a basis for safe practice for patients needing urgent and emergency care. While other mechanisms have emerged, exemptions have remained the cornerstone for all paramedics, from the point of graduation and first registration through to the most senior advanced paramedic roles.

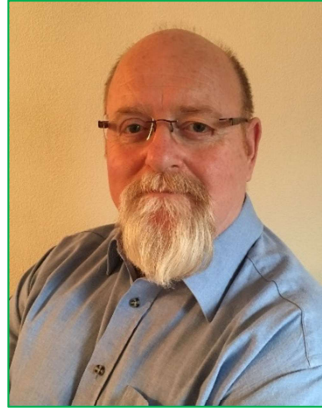
The provision of the guidance in this document is long overdue and its publication brings the paramedic profession into line with other Allied Health Professions (AHPs) who use exemptions and who publish practice guidance on their use. Indeed, this paramedic practice guidance is aligned to the AHPs' documents and we have renewed our intention to work across the AHP community to further develop and refine this and our other documents, such as the practice guidance for prescribing.

The College of Paramedics is indebted to everyone involved in developing guidance that will no doubt enhance the current and future care provided by paramedics. The Specialist Interest Group has provided significant help and support, and our appreciation goes to Imogen Carter who has closely supported the development of this first edition of the guidance.



A handwritten signature in black ink, appearing to read 'John Martin', written over a horizontal line.

John Martin, FCPa  
Chair  
College of Paramedics



A handwritten signature in black ink, appearing to read 'Gerry Egan', written in a cursive style.

Gerry Egan, QAM, FCPa  
Chief Executive  
College of Paramedics

## Introduction

This document provides information which should underpin the decision-making and actions of paramedics who are registered with the Health and Care Professions Council (HCPC) as having access to exemptions within the Human Medicines Regulations to be able to administer listed prescription only medicines (POMs) and pharmacy (P) medicines. *“The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of prescription only medicine containing Heparin Sodium shall be only for the purpose of cannula flushing”*. (Human Medicines Regulations)

This document is ‘guidance’. ‘Guidance’ is information that a paramedic 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 paramedics who are registered with the HCPC and are 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 a paramedic deviates from the advice given in this document when supplying or administering medicines using exemptions in medicines legislation, the clinical judgement for so doing must be carefully recorded. Paramedics must comply with this practice guidance, other guidance issued by the College of Paramedics and with any statutory requirements applicable to the use of exemptions in practice. Failure to do so may put their HCPC registration at risk if concerns are raised about fitness to practise. If a complaint is made against a paramedic, an HCPC fitness-to-practise committee may take account of this document and those to which it makes reference. A paramedic supplying or administering medicines using exemptions will be expected to justify any decision to act outside the terms of this guidance and, in particular, if the paramedic 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 of Conduct, Performance and Ethics<sup>1</sup> and any other relevant HCPC standards relating to medicines.

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 administration of medicines under exemptions by paramedics is not permitted outside of the UK and therefore a paramedic permitted to use exemptions in the UK cannot perform this activity outside of UK jurisdiction.

### ***Standards for the use of exemptions***

The HCPC defines the standards of proficiency that are required by paramedics.

Standards for the use of exemptions by paramedics have been developed by the HCPC.

### ***The scope of medicines use by paramedics***

The purpose of exemptions for paramedics is to support and enhance the delivery of care to patients by promoting safe and appropriate use of the current mechanisms by which paramedics deliver care. As such, paramedics use exemptions to support and enhance the delivery of care aimed at addressing the health and well-being needs of their patients. Accordingly, exemptions mean that paramedics;

*“can administer certain named medicines by injection on their own initiative for the immediate, necessary treatment of sick or injured people (i.e. in emergency situations).”*

Paramedics must only work independently within their scope of practice and the same applies to the use of exemptions. If a paramedic 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 that role.

Paramedics using exemptions must have appropriate education, training and competence to:

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<sup>1</sup> <https://www.hcpc-uk.org/aboutregistration/standards/standardsofconductperformanceandethics/>



- 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 administer medicines under exemptions and/or refer on to another healthcare professional;
- identify appropriate medicines as required, and as indicated in approved clinical protocols that are authorised for use (usually via an organisationally published formulary);
- be sufficiently trained on the use of the specified medicines being considered for administration, including major side effects and interactions. This is of particular importance for new medicines being introduced into practice, and evidence of training and competency should be maintained;
- advise the patient on risks, benefits and outcomes of the medication;
- administer (or supply where authorised and appropriate) medicines with the patient or carer's consent;
- monitor the patient's condition, including any response to the medication administered; and,
- 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. Paramedics who are members of the College of Paramedics 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 full College of Paramedics membership, or ensure they have adequate other indemnity arrangements in place, at the time that treatment or advice is given;
- be practising lawfully; and,

- be practising within the overall scope of the profession.

Paramedic exemptions apply from the point of qualification/graduation and first registration. Paramedics must therefore successfully complete an approved training programme and be registered on the HCPC register before accessing this mechanism in practice.

## **SECTION 1:**

### ***Guidelines on administration of medicines under exemptions***

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

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

The College of Paramedics considers it good practice that, where paramedics are employed, the employing organisation provides clear clinical governance processes, and signs off all protocols and procedures at a senior level, including involvement with senior paramedics (such as consultant paramedics). Where possible paramedics 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.

#### **1 Licence to use exemptions**

- 1.1 In order to legally use exemptions, you must be a paramedic registered with the HCPC
- 1.2 You may only use exemptions once you have successfully completed an HCPC approved paramedic programme which includes specific training on the use of exemptions. The authority to use exemptions is granted as an intrinsic element of paramedics' first-level practice qualification, and therefore there is no annotation on the HCPC register in relation to exemption use.

- 1.3 You should comply with this and other guidance issued by the College of Paramedics and with any statutory requirements applicable to their use of exemptions. Failure to do so may put your registration at risk.
- 1.4 You must only use exemptions for identified medicines within your scope of practice and competency.
- 1.5 You must understand which legal framework you are using to administer medicines and understand which medicines you are permitted to administer within that framework.

## **2 Accountability**

- 2.1 You are professionally accountable for your decisions regarding the 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 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.

## **3 Assessment**

- 3.1 In order to 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 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, including illicit drug use/abuse, that would contra-indicate the use of any medicine
- 3.5 You should ensure you consider the effects of your patient's lifestyle which may affect the safety of the medicines you 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; and,
  - 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 the medicines you use, even though you may be able to take a thorough and appropriate history which leads to a diagnosis.

#### **4 Clinical Need**

- 4.1 You must only administer medicines when you have assessed the patient and there is a genuine clinical need.
- 4.2 You should never administer medicines for your own convenience or simply because a patient demands that you do so.
- 4.3 You should 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; and,
  - Satisfy yourself that you have enough relevant information to make a decision.
- 4.4 You should only administer medicines for patients who are part of your own caseload or under your own care.

## **5 Consent**

- 5.1 You should explain to the patient, or their representative, the role you play in their treatment and seek 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 the prevailing government (UK and devolved nations), College of Paramedics 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 administer. If they do so you should explain the risks, benefits and outcomes of their decision.
- 5.5 Paramedic exemptions are currently limited to administration of medicines, rather than sale/supply.

## **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 has

produced a detailed information governance toolkit<sup>2</sup> 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 (such as USB sticks): 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: These 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;
- 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; and,

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<sup>2</sup> Department of Health (2010) IG Toolkit Version 8 Information Security Assurance Requirement 322  
Detailed Guidance on Secure Transfers (Online) Available at: [LINK](#)

- Faxing: Patient data which is faxed should be done following the NHS IG Safe Haven principles.
- 6.2 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 administration 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 any healthcare provider taking over onward care of the patient (i.e. upon handover at an emergency department). 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.

## **7 Record keeping**

- 7.1 This practice guidance relates specifically to the record keeping of your 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 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 administered, together with relevant details of the consultation with the patient.
- 7.4 Your records should show that you have communicated any treatment regimens involving medicines with the primary healthcare record keeper (usually the GP).

## **8 Evidence based use of medicines/use of medicines in the patient's best interests**

- 8.1 You should ensure that the 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 nationally recognised best practice 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 administering 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 ARHAI Antimicrobial Prescribing and Stewardship Competencies<sup>3</sup> and NICE Guidelines<sup>4</sup> should be used by anyone supplying these medicines to help develop their practice at any point in their professional development in relation to the supply of antimicrobials.

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<sup>3</sup> Department of Health and Public Health England (2013). Antimicrobial prescribing and stewardship competencies. [LINK](#)

<sup>4</sup> National Institute for Health and Care Excellence (NICE) (2015) Guideline NG15: Antimicrobial stewardship: systems and processes for effective antimicrobial medicines use: [LINK](#)



- 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:
- 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; and,
  - Have administered the appropriate dose for your patient's age and weight.

## **9 Delegation**

- 9.1 You may not delegate the administration of any exempt medicine (including controlled drugs) to any another healthcare worker or lay person. Paramedics are solely responsible for the task of administration.
- 9.2 Where another task is being focused on (for example, airway management or haemorrhage control) at the same time as a requirement for a medicine to be given, further medical or paramedical support should be requested to attend the incident (arrangements depend on practice setting).

## **10 Administration of medicines on the recommendation of others (remote authority/delegation)**

- 10.1 You should only use exemptions for patients under your direct care. You should only follow instructions to administer medicines by a doctor or non-medical prescriber remotely where a governed protocol exists, and a clear audit trail can be established.
- 10.2 Paramedics cannot give delegated authority using exemptions. Paramedics who are independent prescribers may give remote authority if they satisfy the requirements in 10.1.

## **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 medicine or diagnosis giving rise to therapeutic need;
  - Any known serious or common side effects of the proposed medicine; and,
  - How the medicine works.
- 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.

## **12 Children**

- 12.1 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 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.
- 12.2 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](http://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](http://www.wales.nhs.uk/sites3/documents/441/englishnsf_amended_final.pdf);
  - Royal College of Paediatrics and Child Health [www.rcpch.ac.uk/publications](http://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](http://www.sign.ac.uk);
- DHSSPS – Medicines Management Standard <https://www.dhsspsni.gov.uk/consultations/medicines-optimisation-quality-framework>; and,
- Department of Health (DH) – Every Child Matters (2004) <https://www.education.gov.uk/consultations/downloadableDocs/EveryChildMatters.pdf>.

### **13 Mixing of medicines**

- 13.1 You must not mix medicines where one is not the diluent of the other. Medicines are rendered unlicensed if they are mixed together prior to administration. The law defines mixing as the combination of two or more licensed medicines together for the purposes of administering them to a patient.
- 13.2 Where medicines are required to be reconstituted using a diluent (saline or water), or another medicinal product is intended as a substrate to carry a medicine (e.g. 10% glucose), this must be documented in the organisational formulary.

### **14 Storage**

- 14.1 Medicines used under an exemption, as with all medicines, must be stored according to the law, and you must also be compliant with any organisational policies and procedures. When not in use, medicines should be stored in lockable containers or cabinets or otherwise returned to a pharmacy department for safe-keeping.
- 14.2 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.
- 14.3 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 storage facilities in place (including specific additional requirements for controlled drugs where applicable).
- 14.4 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.

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

## **15 Transportation of Medicines for use Under Exemption**

- 15.1 In paramedic practice, particularly in ambulance and primary care settings, you may be required to transport medicines while on duty.

- 15.2 Paramedics should follow the guidance issued by the Royal Pharmaceutical Society – “The Safe and Secure Handling of Medicines: A Team Approach<sup>5</sup>”, in particular:

*“Staff engaged in transportation of medicines should be identified, authorised and appropriately trained. Local procedures should also cover situations where staff transport medicines in the course of their duties.”*

- 15.3 Paramedics should be aware of the standards published by the Care Quality Commission (CQC) relevant to the practice setting they are working in. For example, NHS and private ambulance services are inspected against standards in the following document

[http://www.cqc.org.uk/sites/default/files/20160703\\_Ambulance\\_NHS\\_core\\_service\\_inspection\\_framework\\_emergency\\_and\\_urgent\\_care.pdf](http://www.cqc.org.uk/sites/default/files/20160703_Ambulance_NHS_core_service_inspection_framework_emergency_and_urgent_care.pdf)

## **16 Disposal**

- 16.1 You must dispose of used, partially used and unused medicines in accordance with current legislation and your local employer policy. This is of particular importance when disposing of controlled drugs.

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

## **17 Error Reporting**

- 17.1 If you discover that you have made an error in 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.

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<sup>5</sup> Royal Pharmaceutical Society (2005) The Safe and Secure Handling of Medicines: a team approach  
Available at: [LINK](#)

## **18 Reporting unexpected effects and adverse reactions**

- 18.1 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 (either in person as soon as practicable, or via your organisation's incident reporting system/medicines governance team). Yellow cards are found in the back of the British National Formulary and also online at <https://yellowcard.mhra.gov.uk/>.
- 18.2 In addition, you should also inform the patient that they can report adverse reactions independently to the Yellow Card Scheme.
- 18.3 You can also report adverse reactions via the MHRA website at [www.mhra.gov.uk](http://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>.

## **19 Complementary, herbal and homeopathic products**

- 19.1 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.
- 19.2 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.
- 19.3 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 administration of medicines. Paramedics 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. Paramedics must ensure that clinical governance systems are appropriate and work within these.

#### **20 Governance Structures**

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

20.2 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; and,
- Procedures to identify and remedy poor performance.

#### **21 Clinical audit**

21.1 Clinical audit is an important part of clinical governance. You should audit your activities in the use of exemptions and medicines use in general.

21.2 You should audit the patients whom you have administered medicines to under exemptions. You should also audit those patients for whom you took an active decision not to administer medicines under exemptions.

- 21.3 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.
- 21.4 You should seek your patients' experiences of your use of exemptions where possible.

## **22 Administration analysis**

- 22.1 You should ensure that you have information about national guidelines (e.g. NICE guidelines, National Service Frameworks [NSFs]), local guidelines, local agreements and formularies to ensure you make the best decision for your patients.

## **23 Learning from incidents and errors**

- 23.1 You should record all incidents and/or errors within your local reporting systems to facilitate national reporting where required.
- 23.2 You should review incidents within your local team and/or medicines management committee (or equivalent) to enable learning and where necessary change practice.

## **24 Risk Management**

- 24.1 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.

## **25 Continuing Professional Development (CPD)**

- 25.1 You must remain up-to-date with appropriate knowledge and skills to enable you to administer medicines competently and safely within your scope of practice, and according to the mechanisms you are legally able to use.
- 25.2 You should ensure that your CPD is in line with your current or future practice, including any extended roles you undertake.

- 25.3 You should record your CPD in a format that easily enables you to demonstrate your fitness to practice as a paramedic using exemptions.
- 25.4 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.

## **26 Poor Performance**

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

## **27 Links with Pharmaceutical Companies / Conflict of interest**

- 27.1 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.
- 27.2 You must not allow your own, or your employer's (if applicable) commercial or financial interests in a pharmaceutical company or product to influence the way you advise your patients.
- 27.3 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.

## **28 Gifts and Benefits**

- 28.1 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.
- 28.2 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 administration.
- 28.3 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.
- 28.4 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.



28.5 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.

## **29 Checking Registrations and Annotations**

29.1 You must provide evidence of your valid registration as a paramedic with the HCPC to your employer.

29.2 You must only use exemptions in accordance with the published legislation. Paramedics are not given annotation to their registration for the use of exemptions.

## 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 use medicines exemptions
British National Formulary	A joint publication of the British Medical Association and the Royal Pharmaceutical Society. It is aimed at health professionals involved with prescribing, monitoring, supplying and administering medicines.
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.
College of Paramedics	The professional body representing UK paramedics.
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 unused/unwanted medicines 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 pharmacist and may be obtained through a variety of lockable 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 Professions Council	The regulator of allied health, psychology and social work professions including paramedics.
Human Medicines Regulations	The Human Medicines Regulations governs the control of medicines for human and veterinary use, which includes the manufacture and supply of medicines.
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 qualified 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. They may instruct another health professional to administer medicines to patients under the terms of a PSD. An independent prescriber may be a medical prescriber (doctor/dentist only) or a non- medical independent prescriber (nurse, pharmacist, optometrist, physiotherapist, podiatrist, therapeutic radiographer, paramedic).
Licensed 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.
Medicinal product/Medicine	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.
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 Institute for Health and Care Excellence (NICE)	An organisation that provides national guidance and advice to improve health and social care. NICE provides guidance, advice, quality standards and information services for health, public health and social care. NICE also supplies resources to help maximise use of evidence and guidance.
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 unlicensed medicines, mixing medicines and controlled drugs.
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. This definition includes both GSL and P medicines.
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.
Paramedic	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 'paramedic'.
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 prescriber's 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.
PIL	Patient Information Leaflet
Prescription Only Medicine (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 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 POMs 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 produced by the manufacturer and 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 qualified to prescribe medicines as a supplementary prescriber. A person responsible for the continuing care of patients whose conditions have been clinically diagnosed by an independent medical prescriber, prescribing within the requirements of a clinical management plan which has been agreed between the independent medical prescriber, the supplementary prescriber and the patient. .
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 which provides the legislative framework for medicines use in the UK.

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

### ***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. A paramedic 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):** Patient group directions allow healthcare professionals to supply and administer specified medicines to pre-defined groups of patients, without a prescription. This guideline aims to ensure that patient group directions are used in line with legislation, so that patients have safe and speedy access to the medicines they need.

Paramedics must 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 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; and,
- 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 defines 'appropriate practitioner' for the purposes of issuing written prescriptions as a:

- Doctor, dentist or vet;
- Independent nurse prescriber;
- Independent pharmacist prescriber;
- Independent optometrist prescriber;
- Independent physiotherapist prescriber;
- Independent podiatrist prescriber; or a,
- 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.





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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.

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