Paramedics and medicines: legal considerations

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Abstract

This article will cover:

- The relevant legislation relating to medicines and ambulance services
- The restrictions that apply to different organisations or individuals regarding the possession of medicines
- Regulations on the administration and supply of medicines
- Patient Group Directions and Patient Specific Directions.

The law in relation to the possession of medicines, administration to patients and the supply of medicines is separate.

This article also provides guidance to ambulance services and ambulance clinicians on available options to ensure good patient access to medicines in England. The laws described also apply in Scotland and Wales but there are some different national processes. The law both enables and restricts access to medicines. However, it does require interpretation and a pharmacist can help with this. Where interpretation is contentious then organisations may obtain a legal opinion. Legal opinions can also differ, and can only be resolved in court.

Key words
●Medicines ●Medicines legislation ●Patient Group Directions ●Patient Specific Directions

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The Joint Royal Colleges Ambulance Liaiaison Committee (JRCALC) recognise the complexity of the topic of legal considerations for medicines, and requested this article in support of its established clinical guidelines. Its intention is to assist all involved—paramedics, pharmacists, employers and governing bodies—to better interpret these complexities.

The Human Medicines Regulations 2012 (No.1916) (*HMR*) provides an update to the *Medicines Act 1968* (c.67) and has been written to ensure that medicines are appropriately evaluated and safely manufactured. The *HMR* also warrants that the sale and supply of medicines is regulated in order to keep people who are prescribed or given medicines, as safe as reasonably possible. All the organisations and individuals involved in the medicines supply chain need the appropriate licence, certificate or a legal exemption from the regulatory controls. The classification of medicines is given in *Table 1*.

The *Misuse of Drugs Act 1971* (c.38) and its regulations are intended to protect the public from the illicit use of medicines and drugs which have no current medicinal use. Exemptions under the regulations make these medicines (controlled drugs) available to defined groups of organisations and people, and this is discussed later in the article. The classification of controlled drugs is given in *Table 2*. Drugs controlled under the *Misuse of Drugs Act* are placed in 1 of 5 schedules, defined by The *Misuse of Drugs Regulations 2001* (No. 3998) (*MDR*). The more harmful a drug can be when misused, the tighter the controls around its availability and safe storage.

Possession of medicines

The *HMR* defines who can buy and possess medicines, and this is summarised in *Appendix 1*. There is an exemption for the purchase of general sales medicines; however, the supply chain for these medicines is regulated.

NHS ambulance organisations

Medicines

Ambulance Trusts can buy general sale (GSL) medicines (as above) and can be supplied with pharmacy (P) and prescription-only medicines (POM) by a wholesale dealer. As an NHS Trust/Foundation Trust, they are specified in the Regulations (Regulation 249 and listed in Schedule 22).

Controlled drugs

The Home Office updated *The Misuse of Drugs Regulations* in June 2015 and corrected various anomalies. NHS ambulance organisations can now order, stock, supply or offer to supply the controlled drugs listed in Schedules 2–5 of *The Misuse of Drugs Regulations* to paramedics and other healthcare professionals employed by the organisation.

As with hospitals, ambulance services can supply controlled drugs directly to employees for the purposes of immediate treatment of sick or injured persons. An ambulance service cannot supply medicines to other legal entities without an appropriate licence.

The Home Office takes the view that the regulations do not enable ambulance services to distribute controlled drugs to ambulance stations within a Trust, as this is not direct supply to employees. This makes ambulance service Trusts different from NHS hospitals, where the legislation provides for supply to wards. The Home Office has offered the 'solution' of ambulance Trusts obtaining a Controlled Drug Licence, which involves a fee and associated administration.

There is ongoing dialogue between the Ambulance Pharmacists Network and the Home Office about the definition of supply. One legal opinion contends that the distribution of Controlled Drugs within an organisation is direct supply to employees, and therefore a Controlled Drug Licence is not required.

The June 2015 update to the regulations also outlined that from 30 November 2015 a mandatory requisition is required to order Schedule 2 and 3 controlled drugs. When the person in charge or acting person in charge of an ambulance organisation orders controlled drugs then the form must be signed by a doctor or dentist engaged in or employed by the organisation. When an organisation employs a pharmacist responsible for the dispensing and supply of medicines, then the authority is transferred from the person in charge to the pharmacist, just as is the case in a hospital. The record keeping requirements placed on hospitals under the 2001 Regulations also apply to ambulance services.

Individuals and companies

Medicines

The law allows registered paramedics to obtain stocks of the parenteral (injectable) medicines listed for administration in Schedule 17, Part 3 of *The Human Medicines Regulations* (*Table 3*), as well as pharmacy medicines, both under exemptions described in Regulation 250.

These stocks of medicines may be purchased from a wholesale dealer or pharmacy. The legal provisions for individuals do not cover all the medicines in the *UK Ambulance Services Clinical Practice Guidelines* (Association of Ambulance Chief Executives, 2016). The additional medicines not covered, which include the parenteral medicines listed in Schedule 19 of

Table 1. Classification of medicines by the Human Medicines Regulations 2012

General sales (GSL): A medicine that the licencing authority has decided should be available on general sale, e.g. from a supermarket.

Pharmacy medicines (P): This is a default category for medicines which are not a prescription only or general sale medicine. A P medicine can be sold without a prescription but only under the supervision of a pharmacist (Regulation 221). These medicines are usually larger quantities than GSL, but smaller than prescription medicines, so include larger packs of ibuprofen, paracetamol, loratadine and cetirizine, for example.

Prescription-only medicines (POM): These are only available with a prescription from a recognised prescriber. An individual cannot administer a POM by parenterally (except to him or herself) unless they are a defined prescriber (Regulation 214) or they have an exemption under the regulations. The parenteral route is the administration of a medicine which breaches the skin or mucous membrane—normally an injection.

Table 2. Classification of controlled drugs

Schedule 1—No therapeutic value, e.g. cannabis, ecstasy, khat and opium.

Schedule 2—Highly addictive. These are the most strictly controlled and there are defined requirements for ordering, storing, prescription, dispensing and recording these drugs. Some examples are amphetamines, codeine injection, diamorphine and morphine.

Schedule 3—Minor stimulants. These are less likely to be abused than those in Schedule 2, e.g. buprenorphine, midazolam and tramadol. Schedule 3 drugs are less strictly controlled and do not need to be recorded in a Controlled Drug Register. Most are exempt from the safe custody regulations, including midazolam and tramadol. The prescription requirements for these medicines are the same as Schedule 2.

Schedule 4—Exempt from the safe custody regulations and the schedule is divided in two parts:

- Mainly the benzodiazepines, e.g. diazepam and possession is an offence without a prescription or an exemption.
- Anabolic and androgenic steroids, e.g. testosterone. There is no possession offence when part of a medicine.

Schedule 5—Includes weak Schedule 2 drugs that present little risk of misuse and can be sold over the counter as a pharmacy medicine, e.g. codeine and morphine in less than 0.2% concentration.

Table 3. Medicines listed in Schedule 17, Part 3 of the Human Medicines Regulations which paramedics can administer for the immediate, necessary treatment of sick or injured persons. The exception is precription-only medicine containing heparin sodium.

- Diazepam 5 mg per ml emulsion for injection
- Succinylated modified fluid gelatin 4% intravenous infusion
- Medicines containing the substance ergometrine maleate 500 mcg per ml with oxytocin 5 IU per ml, but no other active ingredient
- Prescription-only medicines containing one or more of the following substances, but no other active ingredient
- Adrenaline acid tartrate
- Adrenaline hydrochloride
- Amiodarone
- Anhydrous glucose
- Benzylpenicillin
- Compound sodium lactate intravenous infusion (Hartmann's Solution)
- Ergometrine maleate
- Furosemide glucose
- Heparin sodium (only for cannula flushing)
- Lidocaine hydrochloride
- Metoclopramide
- Morphine sulphate
- Nalbuphine hydrochloride
- Naloxone hydrochloride
- Ondansetron
- Paracetamol
- Reteplase
- Sodium chloride
- Streptokinase
- Tenecteplase

Table 4. Quote from the Group Authority issued by the Secretary of State under The Misuse of Drug Regulations

'2. Registered paramedics, serving or employed at any approved ambulance station, to supply or offer to supply: diazepam and/or morphine sulphate injection (to a maximum strength of 20 mg) and/or morphine sulphate oral to any person who may lawfully have any of these drugs in their possession; and

3. Registered paramedics, serving or employed at any approved ambulance station to possess diazepam and/or morphine sulphate injection (to a maximum strength of 20 mg) and/or morphine sulphate oral for the purposes of that service or employment, subject to and in accordance with the following terms:

- a. Paragraph 2 does not extend to the supply of the drugs, or any offer to supply them, otherwise than as required for the purpose of its administration for the immediate necessary treatment of sick or injured persons
- b. Paragraph 3 does not extend to the possession of the drugs, otherwise than as required for the purposes of their administration for the immediate necessary treatment of sick or injured persons.'

The Human Medicines Regulations and the non-parenteral POM, are only available to paramedics in the course of the business of an ambulance Trust or other body entitled to receive wholesale supplies of an extended range of medicines.

Paramedics who require the extended range of medicines must have a formal relationship with an organisation which can possess these medicines, and that organisation then takes legal responsibility for the medicines and their use.

Controlled drugs

Individuals and companies in England, Wales or Scotland need to apply for a Home Office Controlled Drugs Licence if they wish to produce, supply, possess, import or export controlled drugs. A Group Authority provides an exemption for registered paramedics to possess a limited range of controlled drugs (see *Table 4*).

Registered paramedics are now included in the list of healthcare professionals who require a mandatory requisition form (FP10CDF) to order stocks of Schedule 2 and 3 controlled drugs from wholesalers. A private code is required to use the mandatory requisition form, and this can be obtained from NHS England. The Group Authority (*Table 4)* is effectively an exemption from the *MDR* and enables registered paramedics to possess the controlled drugs listed. The current understanding is that:

- Strength of morphine ampoules is up to 20 mg—the quantity a paramedic can possesses is not limited
- Diazepam refers to all preparations, not specifically injections.

We are in the situation where ambulance Trusts can possess controlled drugs and registered paramedics have an exemption to possess and administer a range of these medicines under the Group Authority. However, there is ongoing discussion and even differing legal opinion on whether ambulance Trusts (without a licence) can distribute these medicines to ambulance stations within the Trust for storage and onward supply to their employees to possess and administer.

Administration of medicines

The *HMR* defines the people who can administer a medicine by the parenteral routes (Regulation 214). As a reminder, the parenteral route is the administration of a medicine which breaches the skin or mucous membrane—normally an injection. A summary of the people who can administer medicines is listed in *Appendix 2*.

Non-parenteral medicines

Oral, rectal, topical and nebulised administration of medicines are all examples of non-parenteral

administration, and the law does not describe who can administer these medicines. Therefore it is not illegal for anyone to administer non-parenteral medicines. However, to be able to administer these medicines, you must first be able to possess them.

NHS ambulance organisations can possess a wide range of medicines, as described earlier. These organisations can enable defined groups of people to administer non-parenteral medicines and they then take responsibility for the safe treatment of patients in the organistion's care. To ensure that the treatment is safe the organisation will define the training requirements for their staff and provide guidelines to identify patients who can be safely treated. Organisations make these decisions locally, and this is why ambulance technicians, community first responders and care assistants in different organisations administer different non-parenteral medicines.

Parenteral medicines

The administration of any medicine can be made in accordance with a prescription. This may be a prescription medicine, labelled with directions, in the possession of the patient or it may be in 'accordance with the directions' of an appropriate prescriber. The prescriber's direction does not need to be in writing; however, a written prescription ensures that what has been prescribed is documented.

Organisations can define who can administer prescribed medicines to patients under their care, as well as who can prescribe, and what precautions should be taken to ensure safe patient care. For example, a Trust may authorise individuals or a group of clinicians to administer end-of-life medicines to patients who have been prescribed them, within defined parameters of training or named medicines and dose ranges.

Exemptions from the regulations

The *HMR* provide exemptions from the restrictions on administration which enable defined groups to administer specified medicines. These are described below.

Schedule 19 Exemption

The list of parenteral medicines which anyone can administer for the purpose of saving a life in an emergency are listed in Schedule 19 of *The Human Medicines Regulations*. The list includes adrenaline injection 1 mg in 1 ml (but only as an intramuscular injection for anaphylaxis), naloxone, glucagon as well as many chemical agent antidotes.

Schedule 19 enables NHS ambulance Trusts to authorise non-registered healthcare professionals, such as ambulance technicians, associate ambulance practitioners and emergency care assistants, to administer the listed medicines for the purpose of saving a life in an emergency. Ambulance organisations take responsibility for the safe treatment of their patients by agreeing the practitioner groups who can administer each Schedule 19 medicine. The organisation does this by having appropriate protocols, training and skills assessment in place. There is no legal reason why any member of staff cannot administer any of the medicines listed in Schedule 19. However, organisations tend not to

Box 1. Practice points

If a prescriber direction is not written, then it is good practice to ensure the prescription is recorded, so that an audit trail is maintained and all parties are protected. It is also good practice to repeat back what you have heard, and to separate out the dosage so that there is no confusion, e.g. 'one five mg' for 15 mg so that it is not confused with 50 mg.

It is good practice for health professionals not to administer medicines prescribed by other healthcare professionals if they are not familiar with the medicine, its effects and side effects. This is because without this knowledge, it is not possible to decide on the benefits or to monitor the patient's response.

For end-of-life medicines it may be appropriate for the clinician to call a prescriber for more information, so that the parenteral medicine can be administered.

Table 5. Schedule 19 of The Human Medicines Regulations: Medicinal products for parenteral administration in an emergency

- Adrenaline 1:1 000 up to 1 mg for intramuscular use in anaphylaxis
- Atropine sulphate and obidoxime chloride injection
- Atropine sulphate and pralidoxime chloride injection
- Atropine sulphate injection
- Atropine sulphate, pralidoxime mesilate and avizafone injection
- Chlorphenamine injection
- Dicobalt edetate injection
- Glucagon injection
- Glucose injection
- Hydrocortisone injection
- Naloxone hydrochloride
- Pralidoxime chloride injection
- Pralidoxime mesilate injection
- Promethazine hydrochloride injection
- Snake venom antiserum
- Sodium nitrate injection
- Sodium thiosulphate injection
- Sterile pralidoxime

enable all staff to administer the medicines because there are not processes or training in place to ensure safe patient care.

Schedule 17 Exemption

The medicines which a registered paramedic may administer for the immediate, necessary treatment of sick or injured persons are listed in Schedule 17 of the *HMR* (*Table 3*). For the administration of these parenteral medicines a paramedic does not need a prescription or the involvement of a prescriber. The exception on the list is medicines containing heparin sodium, as these can only be used for cannula flushing. The legislation is amended from time to time to extend or amend the list of medicines. For example, paracetamol and ondansetron injection were most recently added; tranexamic acid and water for injection are not currently on the list.

A paramedic may supply the medicines listed in the Group Authority to another health professional for the immediate, necessary treatment of sick or injured persons (*Table 4*). However paramedics cannot leave a supply of medicines with a patient for administration at some time in the future, or supply another health professional for use at a later time.

Table 6. Controlled drugs which can be administered and/or supplied under a PGD

Schedule 2	Morphine and diamorphine. Only by registered nurses and pharmacists for the immediate necessary treatment of a sick or injured person—except for treating addiction Ketamine
Schedule 3	Midazolam
Schedule 4	All drugs except anabolic steroids and injectables used for treating addiction
Schedule 5	All drugs

Box 2. Further reading for advice on PGDs

NICE Medicine Practice Guidelines—Patient Group DIrections (MPG2)	www.nice.org.uk/guidance/mpg2
NHS Patient Group Directions website	www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/
'To PGD or not to PGD?—That is the question'	www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/PGD-Legislation-Guidance/PGD-Website-Tools/To-PGD-or-not-to-PGD-that-is-the-question/

Regulation 230 Exemption: Patient Group Directions (PGDs)

A Patient Group Direction (PGD) is defined by the *HMR as* a 'written direction that relates to the sale, supply and administration of a description or class of medicinal product.' A PGD enables named, authorised, registered health professionals listed in Schedule 16 of *The Human Medicines Regulations*, which includes paramedics and nurses, to administer a parenteral medicine for which there is not another exemption to a pre-defined group of patients. For paramedics this will be for any injectable medicines not listed in Schedule 17 or Schedule 19 of the *HMR*. PGDs are ideally suited to the emergency care environment as patients are not identified before presentation for treatment and there is not usually an opportunity for the individualised care a prescriber can offer.

A PGD can be written for a wide range of medicines, and the practice points signposted in the *Box 2* can provide guidance. The controlled drugs which can be administered under a PGD are listed in *Table 6*. Note that tramadol, a Schedule 3 controlled drug, cannot be supplied and administered under a PGD.

A PGD should be drawn up by a multi-disciplinary group involving a doctor, a pharmacist and a representative of the professional group expected to administer or supply medicines under the PGD. It is good practice to involve local Drug and Therapeutics Committees, Area Prescribing Committees and similar advisory bodies. The PGD is signed by a doctor and a pharmacist. The further reading resources in *Box 2* give good advice on PGDs.

When an NHS ambulance Trust is commissioned to provide a service, then any subcontracted company or person will use the PGDs provided by or approved by the commissioned provider to deliver care to patients. This usually means that the private providers will use the ambulance Trusts' PGDs, and will train and sign off their clinicians in the use of the PGD under the guidance of the ambulance Trust. The *HMR* enable independent hospitals to write PGDs (Regulation 231) and more information can be found in the resources listed in *Box 2*.

Patient Specific Directions

A Patient Specific Direction (PSD) is a written instruction, signed by a doctor, dentist, or non-medical prescriber for medicines to be supplied and/or administered to a named patient after the prescriber has considered the individual patient. A PSD can also be an instruction to administer a medicine to a list of named patients where each patient on the list has been individually assessed

by that prescriber. The prescriber must have knowledge of the patient's health, and be satisfied that the medicine to be administered serves the individual needs of each patient. PSDs are not defined in the HMR and more information can be found on the PGD website (see *Box 2*).

There is no requirement for there to be a contractual relationship between the prescriber and the person carrying out the administration. Therefore ambulance clinicians will come across patients with PSDs—the most common examples will be diazepam or midazolam for convulsions, hydrocortisone for adrenal crisis and end-of-life medicines.

Supply of medicines to patients

Prescription-only medicine can be supplied to a patient by a doctor, dentist or pharmacist. The sale and supply of prescription-only and pharmacy medicines should be made at a registered pharmacy premises by or under the supervision of a pharmacist. Non-parenteral medicines are not exempt from the legislation in terms of supply. Therefore a medicine listed in the Schedule 17 or 19 exemptions cannot be supplied to a patient. The exemptions are solely for the administration of medicines. A summary of who can supply medicines is at *Appendix 3*.

Regulation 230 Exemption: Patient Group Directions

PGDs have been described earlier and enable the supply of legally defined medicines. The main restriction for the supply of medicines according to a PGD is the range of controlled drugs (see *Table 6*). More information can be obtained from the PGD website.

Summary

This article summarises the options available to ambulance clinicians and ambulance services to ensure good patient access to medicines.

The organisations and clinicians who can possess medicines are defined by the law. Most clinicians work for organisations that possess medicines and make them available to their clinicians to administer or supply to patients. The organisations are responsible for having policies and procedures in place to ensure patients are treated safely with medicines.

The administration of parenteral medicines is defined by law, and there are legal exemptions which enable ambulance clinicians to administer named medicines; the law is silent on the administration of non-parenteral medicines. A summary of the medicines which can legally be administered by ambulance clinicians is in the '*Key points*' box; organisations make local governance decisions on which medicines they will enable clinicians to administer.

To ensure safe patient care the supply of medicines to patients is restricted. Paramedics can use a Patient Group Direction to supply patients with prescription only and pharmacy medicines.

As pre-hospital models of care evolve, the legal system will need to adapt, and will always follow practice. While the law is well-defined, it will continue to require interpretation and amendment to enable good patient access to medicines.

Conflict of interest: none declared

Key points

- Ambulance Trusts decide which medicines to make available to their staff to use and take responsibility for ensuring safe treatment of patients in their care.
- When medicines can be legally accessed then anyone can administer non-parenteral medicines; a parenteral medicine exempt by Schedule 19 of the Human Medicines Regulations 2012 for saving life in an emergency; parenteral medicines in accordance with a prescription; a medicine in accordance with a Patient Specific Direction.
- Paramedics can also administer a parenteral medicine listed in Schedule 17 of the Human Medicines Regulations 2012; parenteral medicines in accordance with a Patient Group Directions.

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The Misuse of Drugs Regulations 2001 (No.3998) The Stationery Office, London

Futher resource

National Institute for Health and Care Excellence (2016) *Controlled drugs: safe use and management. NG46.* NICE, London

Appendices. Who can posses, administer and supply medicines?

Appendix 1. Summary of who can possess medicines

	General sales	Pharmacy	Prescription only	Controlled drugs
NHS ambulance organisations	Yes	Yes	Yes	Yes—Controlled drugs listed in Schedules 2–5 of The Misuse of Drugs Regulations 2001 (No.3998) Can be suplied to paramedics and other healthcare professionals employed by the organisation
Registered paramedics	Yes	Yes	Limited—parenteral medicines listed in Schedule 17 Part 3 of *The Human Medicines Regulations 2012* (No.1916)	Limited—Controlled drugs listed in the Group Authority
Private ambulance services	Yes	Yes	Schedule 22 of *The Human Medicines Regulations 2012* (No.1916) contains a full list of persons and organisations that are allowed to obtain medicines by way of wholesale	Require Home Office Licence
Members of the public	Yes	Yes	When prescribed	When prescribed

Appendix 2. Summary of who can administer medicines

	General sales	Pharmacy	Prescription only	Controlled drugs
Registered paramedics	Yes	Yes	Non-parenteral medicines Parenteral medicines when prescribed Parenteral medicines listed in Schedule 19 of the *The Human Medicines Regulations 2012* (No.1916) Parenteral medicines listed in Schedule 17 of the *The Human Medicines Regulations 2012* (No.1916)—Exception on the list is medicines containing heparin sodium, which can only be used for cannula flushing In accordance with a Patient Group Direction	In accordance with a prescription In accordance with a Patient Group Direction
Members of the public	Yes	Yes	Yes Non-parenteral medicines Parenteral medicines when prescribed Parenteral medicines listed in Schedule 19 of the *The Human Medicines Regulations 2012*	Yes—when prescribed

Appendix 3. Summary of who can supply medicines

	General sales	Pharmacy	Prescription only	Controlled drugs
NHS ambulance organisations	Yes—to employees who can administer and/or supply	Yes—to employees who can administer and/or supply	Yes—to employees who can administer and/or supply	Without a Home Office Licence: Yes—directly to employees who can possess controlled drugs for the purposes of immediate treatment of sick or injured persons With a Home Office Licence Yes—according to licence
Registered paramedics	Yes	In accordance with a Patient Group Direction	In accordance with a Patient Group Direction	In accordance with a Patient Group Direction
Private ambulance services	Yes—Yes to employees who can administer and/or supply	Yes—to employees who can administer and/or supply	Yes—if they are allowed to obtain medicines by wholesale, then they can supply to employees	Yes—if they are allowed to obtain medicines by wholesale, then employees can administer
Members of the public	No	No	No	No

Correspondence

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