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Information paper

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Introduction

This paper provides background information to explain the use of medicines and prescribing in physiotherapy practice. It covers the basics of medicines law, categories of medicines and medicines frameworks. It also describes the pathway of medicines use and the relevant aspects of scope of practice that need to be considered.

1. Medicines Law

Three different pieces of law control the use of medicines in the UK and these laws overlap. Physiotherapists need to be aware of this because some medicines that they use in practice will be controlled by all three pieces of law.

The Human Medicines Regulations 2012 controls the use of all products defined as medicines and those professions which are authorised prescribers. These regulations consolidated and repealed most of *The Medicines Act 1968.* The remaining parts of The Medicines Act do not directly affect physiotherapists' practise.

The Misuse of Drugs Act 1971 controls all substances, not just medicines that are defined as being specifically open to abuse and dangerous. These substances are collectively referred to as 'controlled drugs'.

*The Misuse of Drugs Regulation*s 2001 categorises controlled drugs to ensure that patients who require controlled drugs for prescribed medical needs can have access to them under special prescribing controls known as 'scheduling'.

The Medicines and Healthcare Products Regulatory Agency (MHRA) is the statutory organisation that enforces medicines law and gives regulatory advice on the use of medicines in practice.

2. Categories of Medicine

All medicines available in the UK market must hold a valid marketing authorisation (also known as a product licence or PL). These medicines are known as *licensed* medicines and should be used within the terms of their product licence. A product licence contains a *summary of product characteristics* (SPC), which provides users with information on how to use the medicine safely and effectively. It is a legal requirement for information leaflets to be supplied with medicines, and specific types of information must be contained within the information leaflet. All licensed medicines fall into one of three categories:

General Sales List medicines (GSL)

These products can be sold 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 (P class) or prescription (POM class). An example of this would be paracetamol, which is limited to 16 tablets under GSL terms, but may be supplied in larger quantities under P or POM terms.

Pharmacy sale medicines (P)

These products can be sold 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 (OTC) medicines as they can be sold and supplied (in some cases only at certain low volumes) without a written prescription for supply.

Prescription only medicines (POM)

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. POMs are restricted to patients whom a health professional has identified as an appropriate recipient. POMs may not be advertised to the general public. All products

(medicine, herbal product or homeopathic preparation) administered by injection and/or considered dangerous because of their ingredients, actions or side effects when taken in the prescribed dose will be legally classed as POM.

An *appropriate practitioner* defined in law as able to write a prescription for medicines is a:

- Doctor, dentist, veterinarian
- Independent nurse prescriber
- Independent pharmacist prescriber
- Independent optometrist prescriber
- Independent physiotherapist prescriber
- Independent podiatrist prescriber
- Independent therapeutic radiographer
- Supplementary prescriber acting under a written clinical management plan (CMP) - (nurse, pharmacist, midwife, podiatrist, physiotherapist, radiographer, optometrist, dietician)

Unlicensed medicines

An unlicensed medicine is one that does not possess a valid UK marketing authorisation (product licence), or is manufactured on the specific instruction of an independent prescriber to meet an individual patient need. Medicines that are prepared in Pharmacy departments to specific instructions (known as extemporaneous preparation or specials) may also not be fully licensed due to the nature of their preparation.

Unlicensed medicines may be products that are still undergoing Phase 3 clinical trials in patients and in this case their use will be strictly controlled by the terms of the clinical trial. Unlicensed medicines may also be created when two licensed products are mixed together prior to administration to the patient. Whilst the resultant product is technically ‘unlicensed’, because the original products are licensed the use of these products should be considered under arrangements for ‘mixing of medicines’.

The term ‘unlicensed medicine’ should not be used to describe a licensed medicine which is being used outside the terms of its product license. The correct term for this description is ‘off-label’ use.

'Mixed' medicines

This is the term used to describe the specific situation when two (or more) licensed products are mixed together prior to administration to the patient to create a new product. A common example in physiotherapy is the mixing of local anaesthetic and corticosteroid in therapeutic injection therapy.

Further information about the mixing of medicines in injection therapy is provided in the CSP Information Paper PD003 "The use of medicines with injection therapy in physiotherapy services."

Controlled Drugs

A controlled drug is a substance that is regulated by both the *Misuse of Drugs Act* and *The Misuse of Drugs Regulations* because it is known to be particularly dangerous or open to abuse. Some medicines that physiotherapists prescribe and/or administer in their practice will be regulated as 'controlled drugs' and will have additional controls in place to monitor their use. *The Misuse of Drugs Regulation*s 2001 categorises controlled drugs to ensure that patients who require controlled drugs for prescribed medical needs can have access to them under special prescribing controls known as 'scheduling'. Controlled drugs are governed by:

Great Britain: The Misuse of Drugs Regulations 2001

Northern Ireland: The Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007.

The Home Office maintains the central list of UK controlled drugs and reviews this list periodically. Changes to the list can only be made after the Advisory Committee on the Misuse of Drugs (ACMD) has advised the Home Office that changes should be made and a full Public Consultation has taken place.

Drugs can be "up-classified" if stronger controls need to be in place, or can be down-classified if a substance has been shown to pose less of a safety risk to patients and the public. The re-classification of substances can affect how physiotherapists prescribe and/or administer controlled drugs, particularly if the drug is moved into a higher classification that has tighter controls on its use.

You must always consult the British National Formulary (BNF) or your local Pharmacist for current advice on the use of controlled drugs.

What do the 'classes' of controlled drugs refer to?

This is the grouping system used by the *Misuse of Drugs Act* to reflect how dangerous the substance is. Drugs are grouped into a 'Class' - either A, B or C according to their risk level, with Class A substances the most dangerous. The 'class' of a drug mainly affects the severity of the penalty for misuse of the drug, and it does not have a practical relevance in clinical practice, but is useful background information.

For example, this table shows the classes of some controlled drugs that physiotherapists may come across in their practice. IP indicates the drug is on the list of 7 controlled drugs for physio independent prescribing.

Class A	Morphine (IP) Morphine Salts Fentanyl (IP) Oxycodone (IP) Any Class B substance that is administered by injection
Class B	Codeine in all preparations Dihydrocodeine (IP)
Class C	Tramadol Diazepam (IP) Lorazepam (IP) Temazepam (IP)

Why can the class of a controlled drug vary?

The route of administration of a controlled drug can affect how dangerous it may be, with intravenous routes regarded as more dangerous. The form of the preparation can also affect how easy it may be to extract the active ingredient, and therefore how easy it may be to abuse the substance. It is easier to extract active ingredients from liquids compared with solids. Therefore, all controlled drugs for injection are Class A, even if the product also exists in Class B or C as a tablet form.

What do the 'schedules' of controlled drugs refer to?

This is the grouping system used by the *Misuse of Drugs Regulations* to reflect the different restrictions that apply to the prescription and monitoring of

controlled drugs used for medical purposes. Drugs are grouped into a 'Schedule' - either 1,2,3,4 or 5, with Schedule 1 having the tightest controls.

For example, this table shows the schedules of some controlled drugs that physiotherapists may come across in their practice. IP indicates the drug is on the list of 7 controlled drugs for physio independent prescribing.

Schedule 1	[research drugs only]	No medical use
Schedule 2	Codeine (>100mg) Dihydrocodeine (IP) Co-codamol Morphine (IP) Morphine salts Fentanyl (IP) Oxycodone (IP)	Special measure in place: - Special prescription - Registers of use - Safe custody arrangements - 28 day prescribing only
Schedule 3	Tramadol Temazepam (IP)	Special measure in place: - Special prescription - Safe custody arrangements for some drugs - Invoice records - 28 day prescribing only
Schedule 4	Diazepam (IP) Lorazepam (IP)	Special measure in place: - Invoice records - 28 day prescribing only
Schedule 5	Codeine (<100mg) Dihydrocodeine (IP) Co-codamol e.g 15/500 or 30/500 Morphine salts	Special measure in place: - Invoice records

<u>Why can the schedule of controlled drug vary?</u>

As well as route of administration, the dose of the controlled drug can affect how potent it may be. All controlled drugs for administration by injection will have a Schedule 2 rating. The schedule rating of a drug depends, amongst other things, on the dose of the active ingredient. Of relevance to physiotherapists, controlled drugs containing morphine or codeine can be either Schedule 2 or Schedule 5 depending on their strength.

You should always check with the Home Office or your local pharmacist for the most up to date information on controlled drug classification. The following information was correct as of 21st May 2015:

Morphine: All morphine products are Class A regardless of route of administration. They will be Schedule 5 if the preparation contains not more than 0.2% morphine and the active morphine cannot be easily recovered from the preparation. All other preparations are Schedule 2.

Codeine: All codeine products are Class B. They will be Class A if the product is for injection. They will be Schedule 5 if the preparation contains not more than 100mg (or 2.5%) codeine per dose unit. All stronger preparations are Schedule 2.

Tramadol: Tramadol is Class C, Schedule 3 controlled drug.

Co-codamol: Co-codamol is a Class B controlled drug. Depending on the strength of dose prescribed, it will be either Schedule 2 or Schedule 5.

What is the impact of controlled drug classification, or reclassification, on physiotherapy practice?

The classification will affect how you can supply and administer and/or prescribe controlled drugs, or medicines containing controlled drugs in your clinical practice. An “up-classification” of a product may mean you have to find an alternative prescribing mechanism, if you do not have the associated independent prescribing rights yourself.

For example, ***Tramadol*** was up-classified to a Class C- Schedule 3 controlled drug in June 2014, from a general Prescription Only Medicine. It is not on the list of 7 controlled drugs that physiotherapists can independently prescribe. It can no longer be supplied and administered under a PGD. Tramadol can only be prescribed by physiotherapists as part of a supplementary prescribing clinical management plan, or be administered by physiotherapists as part of a prescription by another professional with full CD prescribing rights.

For example, ***Codeine*** in is a Class B controlled drug. It is either Schedule 2 or Schedule 5 according to its strength. It is not on the list of 7 controlled drugs that physiotherapists can independently prescribe. Codeine products can only be prescribed by physiotherapists as part of a supplementary prescribing clinical management plan, or be administered by physiotherapists as part of a prescription by another professional with full CD prescribing

rights. Schedule 5 codeine products can be supplied and administered by physiotherapists under a PGD.

What controlled drugs can independent prescriber physio's prescribe?

HCPC annotated physiotherapist independent prescribers can *only* prescribe the following 7 controlled drugs, by the routes listed:

1. Morphine (oral and injectable)
2. Fentanyl (transdermal)
3. Oxycodone (oral)
4. Dihydrocodeine (oral)
5. Temazepam (oral)
6. Diazepam (oral)
7. Lorazepam (oral)

What controlled drugs can supplementary prescriber physio's prescribe?

HCPC annotated physiotherapist supplementary prescribers can prescribe any controlled drug, provided it is listed within the Clinical Management Plan agreed with a Doctor, *before* the prescribing activity occurs.

What controlled drugs can physio's supply and administer under a Patient Group Direction?

Schedule 4 and 5 controlled drugs only.

Can physiotherapists mix controlled drugs prior to administration to the patient?

No. There would need to be a specific provision in the *Misuse of Drugs Regulations* to enable mixing of controlled drugs by physiotherapists. Physiotherapists are only able to prescribe, and administer where appropriate, the limited list of CDs in isolation.

3. Other products

Herbal preparations

Many herbs are known to have medicinal properties. If a herbal product is classified as a medicine, it is subject to medicines legislation and it will have a PL (Product Licence) number printed on its packaging.

The MHRA regulates all over-the-counter herbal products under either PL regulations or the Traditional Herbal Registration (THR) scheme. A THR certification mark also appears on product packaging to help consumers identify registered products. This means the safety of its ingredients has been assessed by MHRA and the product is regulated by MHRA.

For example, Arnica is classed as a General Sales List medicine and so can be sold without a prescription or the direct supervision of a pharmacist, and will have a PL number on any packaging. There are also some Arnica preparations that have THR licences.

Herbal preparations that are unlicensed will not have been assured for safety and quality and the evidence base underpinning their use may be incomplete. MHRA publishes a range of Herbal Information Sheets providing safety information on herbal ingredients. The number of information sheets available will increase as more products are registered under the THR scheme.

All registered herbal preparations are listed on the MHRA website. Some herbal ingredients are prohibited or restricted in medicines, and MHRA publishes a full list of these products at:

https://www.gov.uk/topic/medicines-medical-devices-blood/herbal-homeopathic-medicines

Herbal products classed as medicines will be listed in the British National Formulary
www.bnf.org.uk

Homeopathic preparations

All homeopathic preparations are regulated by medicine legislation. Regulated products may be able to make the medical claim that they can provide relief, or treat minor conditions that would ordinarily be relieved without the supervision of a doctor, and are consequently classed under GSL, P or POM legal categories depending on their action and route of administration.

If a physiotherapist uses these products they may only sell or supply pre-packed P and GSL products that are diluted to at least one part in a million (6c).

Products must be sold from lockable business premises.

It is important to check the product licensing of the preparation as some products are excluded from being GSL because of their intended use; for

example, eye drops will be P because of how they will be used, and products that are to be injected will always have a POM category.

All registered homeopathic preparations are listed on the MHRA website.
https://www.gov.uk/topic/medicines-medical-devices-blood/herbal-homeopathic-medicines

Homeopathic products classed as medicines are listed in the British National Formulary
www.bnf.org.uk

Dietary supplements and foodstuffs

You must carefully consider the nature of the product, as depending on its ingredients it may be classified as a medicine, a medical device or a food product.

Some products to treat obesity such as appetite suppressants and/or lipase inhibitors are POM medicines and must only be supplied in accordance with an appropriate prescription. Other products used to manage obesity such as fat-binders and/or gastric bands are classed as 'medical devices' which do not require prescription, but are subject to stringent safety regulations, and may require specific training in order to supply them safely.

Vitamins and other dietary supplements are not considered medicines or devices but may be considered food products, and will be subject to the relevant food standards laws. A food product cannot make any medical claim unless substantiated by robust medical evidence.

If a product is not clearly identifiable as either a medicine, a device or a food stuff, then there is no guarantee as to its efficacy or safety. You should be able to access a full ingredient list; in some cases products may contain unidentified, or even illegal, stimulants or other substances.

Physiotherapists may incorporate advice on food supplements and dietary supplements only to the extent that it falls within the overall scope of physiotherapy practice and that the therapist is educated, trained and competent to give such advice.

Patients requiring dietary assessment should be referred to a registered dietician, for a full assessment of their needs and appropriate dietary advice as appropriate.

Medical devices

There is often no clear boundary between a *medicinal product* and a *medical device*.

Medical devices may include items such as instruments, apparatus, appliances and equipment. Medical devices also include products such as injectable joint lubricants, gastric bands, and some saline products. Medical devices are regulated separately from medicines under their own regulations: *https://www.gov.uk/topic/medicines-medical-devices-blood/medical-devices-regulation-safety*

Most medical devices placed on the UK market must comply with device-specific legislation, which has been adapted into safety regulations under the UKConsumer Protection Act. Medical devices are categorised into classes in which the level of regulatory control applied to the device is proportionate to the degree of risk associated with the device.

It is important for physiotherapists to understand this distinction between a *medical device* and a *medicinal product* as they are regulated by different statutory frameworks: for example, the distinction between '*sodium chloride 0.9%-for- injection'* (POM) and '*sodium chloride 0.9%-for-irrigation'* (medical device). Whilst the two substances are biologically the same preparation, their mode of use makes them subject to different legal frameworks.

Devices that are injected into patients are likely only to be supplied upon written prescription to a health professional qualified to use such devices, depending on manufacturer requirements and the local Pharmacy policy.

Human blood and blood products are subject to a separate framework of regulation.

4. Medicines Frameworks

All medicines must be used within a valid framework to ensure that they are supplied and administered to patients in a safe manner with suitable controls in place.

Annexes 1 and 2 summaries the permitted medicines frameworks for each of the UK prescribing professions.

Patient Specific Direction:

This is a supply and administration framework.

A PSD is a written or electronic instruction from a prescriber for a medicine to be administered to an individually named patient. It relates to the relationship

between the prescriber and another professional. A physiotherapist 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.

Examples of a written instruction include 1) the traditional prescription 2) an instruction written in the patient's medical records 3) an instruction written on a hospital drug chart or 4) an instruction given in a letter written from a doctor to a physiotherapist.

There is no legal requirement for a face-to-face consultation between a prescriber and their patient to occur before a prescription is written, but the prescriber must have sufficient information to make a safe prescribing decision, particularly when prescribing remotely and/or on the recommendation of another health professional.

A physiotherapist may administer the medicines prescribed by another professional authorised to write a prescription, and this includes those written by other non-medical independent or supplementary prescribers. Any non-medical independent of supplementary prescriber may also write a prescription and ask another person to administer the medicines which have been prescribed.

Patient Group Direction:

This is a supply and administration framework.

A senior doctor and a senior pharmacist, in conjunction with the physiotherapists who will use the PGD, 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.

In order to be valid, a PGD must meet specific legal criteria. This includes the requirements that only **licensed** medicines are included in a PGD, that the health professional [physiotherapist] named on the PGD is registered with the appropriate statutory regulator [HCPC], and that the supply and administration of the drugs listed in the PGD is not delegated to anyone else.

The physiotherapist must supply and administer the medicine in accordance with the instructions that are written within the PGD.

PGDs are valid in all NHS hospital and primary care settings. Non-NHS independent clinics may also authorize their own PGDs subject to being registered with the Care Quality Commission (CQC). In reality, private physiotherapy practices are unlikely to meet the requirements to develop their own PGDs unless they are part of a CQC registered organisation, or are otherwise formally contracted to provide NHS services in which case the NHS PGD would be valid.

PGDs can include medicinal products for use outside their licensed indications (often referred to as “off-label”) if their use is exceptional and justified by best clinical practice. Off-label use only applies to medicines that are already licensed. However, clinicians should be aware that if information given in a product’s Summary of Product Characteristics (SPC) states that a certain technique/action is not advised then members should consider an alternative approach in the first instance unless ‘off-label’ use really is justified. PGDs cannot be used for the administration of pharmacy-prepared products as these are not fully licensed; i.e. you cannot ask the Pharmacy department to mix the products for you in advance of your use of them. PGDS can also be used for Schedule 4 and 5 controlled drugs.

Mixing two licensed medicines together before administration creates a new unlicensed product which cannot be administered under a PGD. It is not the ‘off-label’ use of two licensed medicines. Whilst UK medicines law has been radically consolidated in 2012 to reflect modern UK practice, European medicines law takes precedence over UK law. European law does not allow any type of unlicensed medicine to be used under a PGD and this position is unlikely to change.

PGDs are governed UK wide legislation which is now within s229-234 and Sch 16 The Human Medicines Regulations 2012.

NICE issues guidance for the use of Patient Group Directions: Medicines Practice Guidance MPG2 – Patient Group Directions (2013):https://www.nice.org.uk/guidance/mpg2/chapter/Summary

NICE also provides a competency framework to help registered practitioners able to use PGDs demonstrate they are safe to do so: https://www.nice.org.uk/guidance/mpg2/resources

PGDs may not be suitable to use for post-registration training environments. This is because PGDs should only be used by registered health professionals who are fully trained and competent. Where health professionals who are not independent prescribers are developing a new skill through a post-registration programme, for example injection therapy, the Trust may make a local decision that the trainee-injector cannot be added to the PGD whilst they undergo their training, even though they are a fully registered health professional who would otherwise be permitted to be named on the PGD.

It may be helpful for trainee-injectors to compete the PGD competency framework early in their injection therapy training. This may enable trainee-injectors to be added to a PGD whilst they continue the supervised clinical practical aspects of injection therapy training. If this is not possible trainee-injectors will need to use a PSD to access the medicines needed to provide injection therapy until they can prove that they have passed their injection-therapy course and demonstrated full training and competence in this area.

Supplementary Prescribing

This is a partnership prescribing framework.

The supplementary prescriber works in partnership with a doctor to prescribe the medicines needed by an individual patient for the management of their condition using a written document called a *Clinical Management Plan (CMP).* The names of the medicines permitted to be prescribed must be listed in a written Clinical Management Plan that is created before prescribing occurs.

The CMP must contain the following details:

- patient's name
- the illness/condition(s) that may be treated by the supplementary prescriber

- the effective date and the review date
- the medicines to be prescribed/administered
- any restrictions to prescribing/administration
- relevant allergy warnings
- notification arrangements for adverse reactions and circumstances when the supplementary prescriber must seek advice of the doctor.

Supplementary prescribing can be used to prescribe licensed medicines, unlicensed medicines, mixed medicines and all controlled drugs. Supplementary prescribing is an advanced practice activity requiring additional qualification and HCPC annotation.

Supplementary Prescribing is governed by:

England: s20, s215, Sch 14The Human Medicines Regulations 2012

Wales: NHS Regulations (Wales) (W.19) (SI 2007/205)

Scotland: National Health Service (General Medical Services Contracts) (Scotland) Amendment Regulations 2005 (No. 337) (SI 2005/337)

Northern Ireland: Statutory Rules of Northern Ireland (SI 2007/348).

Independent Prescribing:

This is an autonomous prescribing framework.

The prescriber works within their own scope of practice to prescribe the medicines a patient needs for the management of their condition(s).

Independent prescribing can be used to prescribe licensed medicines, unlicensed medicines, mixed medicines and controlled drugs. The extent of what can be prescribed will depend on the profession of the prescriber. Independent prescribing is an advanced practice activity requiring additional qualification and HCPC annotation.

Any non-medical independent of supplementary prescriber may also write a prescription and ask another person to administer the medicines which have been prescribed.

Independent Prescribing is governed by:

England: s20, s214, Human Medicines Regulations 2012

Wales: The National Health Service (Physiotherapist, Podiatrist or Chiropodist Independent Prescribers) (Miscellaneous Amendments) (Wales) Regulations 2014

Scotland: The National Health Service (Physiotherapist, Podiatrist or Chiropodist independent prescribers) (Miscellaneous Amendments) (Scotland) Regulations 2014

Northern Ireland: The Pharmaceutical Services (Amendment) Regulations (Northern Ireland) 2014

The scope of physiotherapy prescribing

The purpose of individual physiotherapist-prescribing is to support and enhance the delivery of tailored physiotherapy interventions to patients that are aimed at addressing the health and well-being needs of individuals and groups related to movement, physical performance and human functioning in their widest sense, or to support the delivery of care pathways that can be effectively delivered by a physiotherapist.

Physiotherapist prescribers should not be asked to prescribe for patients to make up for short-falls in other professional prescribing groups.

Physiotherapy as a profession covers a very broad and diverse range of specialties, and therefore prescribing may be required by a physiotherapist working in any of these specialist areas. For example, there may be a need for a physiotherapist to prescribe in neurological rehabilitation, musculoskeletal pain management, women's health services, elderly care etc. Individual physiotherapists who develop specialist expertise tend to do so in one area of clinical practice only. Therefore, whilst the prescribing activity of the profession as a whole may appear broad and diverse, the individual activities of any given prescribing physiotherapist will be focused only within their chosen specialist area of practice.

Physiotherapists are not permitted to prescribe medicines for animals.

The scope of independent prescribing practice by physiotherapists is:

> "*The physiotherapist independent prescriber may prescribe any licensed medicine from the BNF, within national and local guidelines for any condition within the practitioner's area of expertise and competence within the overarching framework of human movement, performance and function. They may also mix medicines prior to administration and may prescribe from a restricted list of controlled drugs as set out in Regulations."*

This means physiotherapists cannot prescribe medicines for cosmetic purposes.

Emergencies to save life:

Section 238 and Schedule 19 of The Human Medicines Regulations allow that any person may administer a limited list of specified POMs to another person without prescription in order to save their life in a genuine emergency. For example, the main purpose of this legislation is to allow a member of the public to administer otherwise POM medicines to individuals. An example would be where a member of the public administered adrenaline in the case of an allergic reaction to a patient who carried an Epipen (or similar) with them.

The only medicine on the permitted emergency list relevant to physiotherapists is *Adrenalin 1:1000 up to 1mg for intramuscular use in anaphylaxis.*

Where physiotherapists may be required to administer adrenalin to manage anaphylactic reaction as part of their work and the doses or administration regime will be more than *1:1000 up to 1mg,* then a PGD or prescribing framework should be in place. This is because these frameworks permit the adrenalin to be administered up to the limits required, rather than be restricted to the upper limit of 1mg which is all that is permitted by the 'emergency use' schedule.

5. Types of Prescriber

Medical Prescriber

A doctor who can independently prescribe all licensed and unlicensed medicines, and all controlled drugs, and who may instruct another health professional to administer such medicines to patients in accordance with their instructions.

Non-Medical Prescriber

A registered health professional who belongs to one of the professions permitted in medicines legislation to act as either a supplementary or independent prescriber.

Supplementary Prescriber

Supplementary prescribers are certain registered health professionals who are permitted to prescribe medicines in partnership with a doctor using a

written document called a *Clinical Management Plan (CMP).* They can also administer medicines, and give direction (i.e. delegate) that the administration of medicines is done by someone else.

Independent Prescriber

Independent prescribers are certain registered health professionals who are permitted to prescribe from a range of medicines within their scope of practice. They can also administer medicines, and give direction (i.e. delegate) that the administration of medicines is done by someone else.

6. Pathway of medicines use

Medicines use involves the following stages:

Prescribing

Prescribing is issuing a written prescription for the medical treatment of a single individual by an *appropriate practitioner*. The law requires that POM medications may only be supplied against a written prescription, and for a prescription to be legally valid they must:

- be written in ink or other indelible material (if the medicine is subject to the Misuse of Drugs Regulations[13]) or by carbon copy
- be indelibly signed by the prescriber

and include:

- the address of the prescriber
- the date of prescription
- the name , address (and age if under 12) of the patient
- the name of the drug, dose and dosage

Controlled drugs are subject to additional prescribing controls and restrictions depending on the schedule of the drug. The only exception to the legal written requirements for prescriptions is where the medicines are for use in hospitals, in which case *written direction* by an appropriate practitioner is sufficient. This means that instructions given on drug charts or in hospital notes are valid.

A *prescriber* is an *appropriate practitioner* authorised by law to issue *prescriptions*. The law recognises different types of prescriber who are granted different legal prescribing rights.

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.

Dispensing (Supply)

Pharmacists control the supply of medicines to either patients or other health care professionals by the process of *dispensing*. Dispensing is the stage in a medicine's life cycle where it is released for use and thus no longer subject to any specific storage-control requirements. This part of the medicine pathway is regulated by complex legislation that is of relevance only to pharmacists.

Medicines may be supplied in two ways:

- against a valid prescription
- by wholesale dealing.

Medicines may be supplied to individual patients for their own use in accordance with the terms of a valid prescription issued by an appropriate practitioner, or by the terms of a valid PGD. Under the terms of the Human Medicines Regulations, physiotherapists are defined as *appropriate practitioners* to be supplied with, and to supply medicines to patients, in these ways.

Medicines may also be supplied to organisations and individual professionals in bulk for those organisations/persons to subsequently supply to their own patients. This is known as *wholesale dealing* and is regulated by the Human Medicines Regulations. At the current time, the only individual practitioners entitled by law to receive bulk prescriptions of drugs by way of wholesale dealing are doctors and dentists.

Physiotherapists may only receive bulk supplies of medicines if an NHS or private organisation employs them and as part of their job they are required to supply/administer medicines under a PGD authorised by that organisation.

Administration

Medicines may be administered to patients by any medicines framework described earlier. All frameworks except a PGD allow for delegated

administration of the medicine. Where a physiotherapist delegates the administration of a medicine to another person, the physiotherapist is accountable for the decision to delegate and whether or not it is appropriate to delegate an activity, but they are not responsible for the outcome of that delegated activity as performed by the other person.

Patient acceptance

A patient must be advised of all the possible risks, benefits, and outcomes of using a particular medicine that would be considered as significant and material to their individual circumstances, so that a patient is able to make an informed decision as to whether to consent to take a certain medicine. This would certainly include being advised of any patient information leaflet contained with the medicine and being informed whether the medicine was licensed for use in the proposed manner.

Disposal of medicines

Procedures for safe removal and destruction of unwanted, damaged, out-of-date or part-used medicines, including any medicine that has not been administered to a patient, are required for all locations where medicines are stored and administered.

When carrying out these activities, safety, security, legal requirements and local environmental regulations must be considered for each product. Local pharmacy departments and/or Trust medicines management committees will provide specific detail for local circumstances.

Delegated activities

The act of prescribing medicines cannot be delegated and may only be performed by an ‘appropriate professional’ who is appropriately registered to prescribe. The supply and administration of medicines may be delegated by the prescriber to another person, if the prescriber is not able to administer the medicines themselves. The supply and administration of medicines within a PGD cannot be delegated to anyone other than the individuals named within the PGD.

7. Scope of practice and medicines use

A physiotherapist may practise any activity that falls within the four pillars of practice and the overall philosophy of the profession, provided that they are appropriately educated, trained and competent to practise in the way that they do.

The supply and administration of medicines is accepted as an integral part of the practice of those physiotherapists who choose to develop knowledge, skills and experience in this area.

Physiotherapists may independently and autonomously manage the whole patient pathway of conditions referred to them without the need for the patient to unnecessarily see a range of practitioners for any one condition. Prescribing further enables physiotherapists to offer a greater range of skills as first contact practitioners.

Developing the knowledge, skills and experience to safely supply, administer and prescribe medicines is a post-registration activity that may be developed by physiotherapists. However, all physiotherapists should have sufficient competence to advise patients on where to obtain appropriate medicines advice, and there is an expectation that health professionals will be able to give appropriate advice to patients on the medicines that may be beneficial for conditions referred to them – e.g. as in the National Institute for Health and Care Excellence (NICE) guideline on osteoarthritis.

Physiotherapists may be using medicines in any of the following ways:

1) Giving advice on medicines use

Advice is the act of giving information to service users pertaining to aspects of the condition for which they are seeking intervention, and this may include giving advice on the medicines a patient is currently taking or which may be of benefit in the future. There is a difference between *giving advice* and *prescribing* (see Glossary).

Before any professional can advise on the use of medicines, it is imperative that the professional has the appropriate knowledge of the medicine, its pharmacology and dynamics and how it is handled in the body, as well as the legal framework surrounding medicines. They should also understand where,

and from whom, appropriate medicines advice and information can be obtained.

In particular, the physiotherapist should refer the patient to the Summary of Product Characteristics (SPC) supplied with any product.

It is also important to understand whether the item is question is a *medicine* or a *device*.

The level of advice given may depend on whether or not the physiotherapist is qualified as a prescriber, and the legal category of the medicine.

Non- prescribers

Some physiotherapists may have knowledge from their undergraduate and/or postgraduate study on the pharmacology of medicines and their effects. Many physiotherapists have detailed knowledge of the medicines they will encounter in their clinical areas.

Physiotherapists who can demonstrate this competence may give patients general advice on the effects of medicines, e.g. general side-effects of non-steroidal anti-inflammatory drugs (NSAIDs) that may be applied to a whole population, but should always advise patients to seek the advice of an independent prescriber or pharmacist before taking, changing or stopping any POM medicine, or if they have any specific concerns with any medicine.

Giving specific tailored advice regarding the use and interaction of POM medicines for a named patient is only appropriate within a PGD or supplementary prescribing framework.

Examples in practice:

- It would be acceptable for a physiotherapist to recommend taking paracetamol as a simple analgesic for musculoskeletal pain, as the evidence for this intervention is widespread e.g. there is a NICE guideline[34] on the matter.
  Also, paracetamol is on the General Sales List (GSL) and available without supervision from an independent prescriber or pharmacist at small purchase volumes.
- It may also be within an individual's scope of practice to recommend that a patient seeks a prescription from their GP for a named POM if the physiotherapist has clear knowledge of the evidence and current practice for the use of the named POM and is working with the relevant particular patient group on an ongoing basis.

This advice would then be followed with a recommendation to discuss the use of this particular drug with their GP (or pharmacist as appropriate).

- If a physiotherapist notes that a patient is taking a medicine not in accordance with the directions on the packet/prescription, it would be appropriate for the physiotherapist to remind the patient to take the medicine as directed and if necessary to show the patient what the correctly prescribed dose is.
- If a physiotherapist is concerned about the effects of a medicine on their patient, they should refer the patient to the person who prescribed the medicine or to a pharmacist, and if necessary contact the patient's doctor themselves.

It is not appropriate to change any parameter of a POM such as the dose or frequency of use, or to recommend stopping a course of any POM medication, without discussing this first with the original prescriber.

As with all medicines, for NHS-employed physiotherapists it is appropriate to discuss medicines issues with the Trust's pharmacy department, as they will help suggest what may be advised to patients. For example, a physiotherapist may wish to provide generic information to patients on e.g. glucosamine, as many patients ask for information on this product without actually being prescribed it.

Pharmacy departments may also wish to approve any general patient information leaflet that is given to patients which contains medicines information.

Prescribers

An *independent* prescriber has full autonomy over their prescribing decisions and may advise on medicines use within their personal scope of practice.

A *supplementary* prescriber may only prescribe and modify POM medicines for patients for whom they have a written clinical management plan (CMP) in place. This CMP will have been agreed with a doctor and will define what may be prescribed and the parameters within which changes to prescription may be made. They may advise a patient on any medicines within their scope of practice, but must not prescribe them until the CMP has been amended.

They cannot modify or terminate a POM medicine's use without a CMP in place.

2) Giving medicines to a patient in an emergency

Section 238 and Schedule 19 of The Human Medicines Regulations allow that any person may administer a limited list of specified POMs to another person without prescription in order to save their life in a genuine emergency. For example, a member of the public can administer adrenaline in the case of an allergic reaction to a patient who carries an Epipen (or similar) with them.

The only medicine on the permitted emergency list relevant to physiotherapists is *Adrenalin 1:1000 up to 1mg for intramuscular use in anaphylaxis.*

Where physiotherapists may be required to administer adrenalin to manage anaphylactic reaction as part of their work and the doses or administration regime will be more than *1:1000 up to 1mg,* this should be in accordance with the terms of a PGD, so that the adrenalin may be administered in accordance with the PGD and is not restricted to the upper limit of 1mg permitted.

Other situations may be encountered, where a physiotherapist may have to consider if they need to give medicines to patients:

3) Where the patient has their medication with them

If a patient brings their own medication in with them to a physiotherapy class or clinic, then the medicine will have already been prescribed for the patient by a prescriber and this will include instructions on how and when to take the medicine.

If an emergency arose in this context, a physiotherapist would simply be assisting a patient to take their medication correctly as prescribed.

In order to do this appropriately it would be necessary for the patient to bring the medicine to the class or clinic in its proper packaging as dispensed by a pharmacist so that the physiotherapist can see the instructions for administration.

Provided the physiotherapist is educated, trained and competent in the administration method required (e.g. setting up a nebuliser) then they may administer the medicine in accordance with the prescription.

If bringing medicines to a class or clinic is a common occurrence, it would be good practice to check that all medicines are present and correct and that the patient gives you any specific information re administration prior to the start of the class or clinic.

Where there are no instructions provided with the medicine, i.e. the patient brings in the medicines, but not the packaging that includes the instructions on how to take it, then the decision to administer in an emergency is a matter for professional judgment combined with any employer policy on administration of prescribed medicines in these circumstances.

4) Where the patient does not have their medication with them

If patients become acutely unwell and do not have their own medicines with them, then the law allows for a specified list of medicines that can be administered via injection by anyone in an emergency to save life if they are available at the time. Of relevance to physiotherapists, this list includes adrenalin.

In an employed situation, the employer usually has a locally developed protocol or PGD to enable staff to administer such medicines within a framework that provides both safety and accountability for the staff member and timely treatment for the patient.

If a patient becomes acutely unwell and does not have their own medicines with them, then non-injectable medicines - such as oxygen or bronchodilators – may be used if the employer has a policy and guidance in place for staff to follow.

Individual physiotherapists would need to consider whether using such medicines is commensurate with appropriate physiotherapy practice in the relevant clinical setting.

Glossary of terms

Administration	Process by which a medicine is introduced into, or applied on to, 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 chose whether or not to act on the advice given.
Appropriate practitioner	A 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.
Black-triangle drugs	New licensed medicines under intensive monitoring by MHRA and subject to special adverse incident reporting requirements. MHRA issues a monthly list of medicines subject to black-triangle status.
Clinical management plan (CMP)	A written plan (which may be amended from time to time) relating to the treatment of an individual patient which is agreed by • The patient • The independent prescriber • The supplementary prescriber who is to prescribe, supply and administer (including delegated administration) medicines under the plan. Licensed medicines including off-label and black-triangle products, unlicensed medicines and controlled drugs may be included in a CMP. A CMP may be for a named medicine or a group of medicines e.g. non-specified NSAIDs.
Controlled drug	A medicine subject to control by the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.
CSP	The Chartered Society of Physiotherapy
Dispensing	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.

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.
GSL	General Sales List. A medicine for which all active ingredients are listed in the relevant Medicines (Products Other Than Veterinary Drugs) (General Sales List) Order, or are so classified in their marketing authorisation.
HCPC	Health and Care Professions Council
Independent prescriber (IP)	A professional who is registerd on the appropriate statutory register for their professional group and against whose name is recorded an annotation signifying that they are qualifed to prescribe, supply and adminsiter medicines as an independent prescriber. A person 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 person to administer the medicines under the terms of a PSD.
KSF	Knowledge and Skills Framework
Licensed medicine	A medicine with a valid marketing authorisation (product licence) in the UK.
Marketing authorisation (MA)	Formal approval by 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 device	All products, except medicines, used in healthcare for the diagnosis, prevention, monitoring or treatment of illness or disability. Examples include X-ray and other imaging equipment, pacemakers, artificial joints,

	anaesthetic equipment, infusion equipment, beds, wheelchairs, and surgical dressings.
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	Any substance or article (but not instrument, apparatus or appliance) which is manufactured, sold, supplied, imported or exported, for use wholly or mainly in either or both of the following ways: • administration to one or more human beings (or animals) for a medicinal purpose • used as an ingredient, by a practitioner, pharmacy or hospital, in the preparation of a substance or article which is to be administered to one of more human beings for a medicinal purpose.
Medicinal purpose	Any one or more of: • treating or preventing disease • diagnosing disease or ascertaining the existence, degree or extent of a physiological condition • contraception • inducing anaesthesia otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by terminating, reducing, postponing, increasing or accelerating the operation of that function, or in any other way.
Medicine	A substance that claims to, or has the actual function to, treat or prevent disease in humans or animals.

Mixing	The combining of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient
MHRA	Medicines and Healthcare Products Regulatory Agency
NHS	National Health Service
NHS prescription charge	Fee paid by patients for medicines or other treatments prescribed for them by an NHS appropriate practitioner. Some patients are exempt from paying prescription charges and receive the medicines free of charge.
Non-medical prescriber (NMP)	A nurse, pharmacist and some allied-health professionals 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 and qualified to prescribe, supply and administer medicines as either an independent or supplementary prescriber. They can prescribe any licensed medicine for any medical condition including some controlled drugs in certain circumstances. They will be restricted by the British National Formulary, local formularies and local/national guidelines e.g. NICE. An NMP may instruct another professional to administer medicines to a patient under the terms of a PSD.
Off-label	Use of a medicine outside its licensed indications (as contained within the SPC). Off-label use only applies to medicines that are already licensed i.e. hold a valid Marketing Authorisation.
Over-the-counter (OTC)	A medicine that can be supplied without a written prescription from a variety of outlets, including self-selection without supervision, by a patient.
P	Pharmacy-only

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. In order to be valid, a PGD must meet specific legal criteria. These include the requirements that: only licensed medicines are included in a PGD the health professional (e.g. physiotherapist) named on the PGD is registered with the appropriate statutory regulator (e.g. HCPC) the supply and administration of the drugs listed in the PGD is not delegated to anyone else. PGDs tend to be used in hospital and primary care settings but are also valid in other non-NHS clinical settings. PGDs can include medicinal products for use outside their licensed indications ('off-label') if their use is exceptional and justified by best clinical practice. Off-label use only applies to medicines that are already licensed. PGDs cannot be used for the administration of pharmacy-prepared products as these are not fully licensed.
Physiotherapist	A person who is registered on Part 9 of the HCPC register under article 5 of the Health and Care Professions Order 2001 and entitled to practise using the protected title of 'physiotherapist'.
POM	Prescription Only Medicine. Such medicines may only be supplied and administered against a valid written prescription.
Patient Specific Direction (PSD)	A written instruction from a doctor, dentist or other independent/supplementary prescriber for a medicine to be supplied or administered to a named patient by another health professional. The patient must be individually identified on the PSD. The written instruction must be signed and dated by the doctor/dentist or other independent/supplementary prescriber.

	Unlicensed medicines may be supplied and/or administered under a PSD provided it has originated from a medical independent prescriber. A PSD is not a standard proforma that is drawn up by a [physiotherapist] for a doctor to sign. This may be one way of indicating the desired prescription, but the doctor is free to amend or alter this in any way as they see fit, as they will have accountability for any medicines prescribed.
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. At the current time for physiotherapists, this is limited to supplementary prescribers. **GENERAL**: to authorise in writing, in the appropriate manner, the supply and administration of any medicinal product(s), for use by a named patient, at public expense. 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.
Product Licence (PL)	Formal approval by MHRA to place a medicinal product on the UK market. Now known as a 'marketing authorisation'. 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 PL is known as *off-label* use of the product.
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, supply and administer medicines as an 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	Legal 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.
Wholesale dealing	Bulk supply of medicines to doctors, dentists and NHS or registered private organisations for them to subsequently sell or supply to their named patients.

Annex 1: Summary chart of permitted medicines frameworks for the prescribing UK health professions 2016

Profession	*PGD*	*Supplementary Prescribing (SP) within a CMP*	*Independent prescribing*				
			Licensed	*Off Label*	*Mixing*	*Controlled Drugs*	*Unlicensed*
Nurses	*Licensed medicines* *Off label use of licensed medicines* *Schedule 4-5 controlled drugs* *Schedule 2 morphine/diamorphine for sick and injured* *NO MIXING*	Licensed medicines Off-label use of licensed medicines Mixing of licensed medicines including all controlled drugs Schedule 2-5 controlled drugs Unlicensed medicines	Full Formulary	Full Formulary	Permitted Including mixing Schedule 2-5 controlled drugs	Full Formulary Schedules 2-5 except diamorphine, cocaine and dipipanone for addiction	Yes
Pharmacists			Full formulary	Full formulary	Permitted Including mixing Schedule 2-5 controlled drugs	Full Formulary Schedules 2-5 except diamorphine, cocaine and dipipanone for addiction.	Yes
Optometrists	*Licensed medicines* *Off label use of licensed medicines* *Schedule 4-5 controlled drugs* *NO MIXING*		Full formulary but not injectables	Full formulary but not injectables	No	No	No
Physiotherapists			Full formulary	Full formulary	Permitted No Mixing controlled drugs	Limited Formulary of 7 drugs	No
Podiatrists			Full formulary	Full formulary	Permitted No Mixing controlled drugs	Limited formulary of 4 drugs	No
Therapeutic Radiographers			Full Formulary	Full Formulary	Permitted No Mixing controlled drugs	Limited list of 9 tbc	No
Diagnostic Radiographers			No	No	No	No	No
Dieticians			No	No	No	No	No
Paramedics		No	No	No	No	No	No

Annex 2: Summary chart of medicines frameworks for all UK medical and health professions 2016

Profession	PSD	PGD incl Sch 4-5 controlled drugs	Exemptions	Supplementary Prescribing (SP)	Independent Prescribing (IP)	IP - Mixing	IP- Controlled Drugs	IP -Unlicensed medicines
Doctors	N/A	N/A	N/A	N/A	*	*	*	*
Dentists	N/A	N/A	N/A	N/A	*	*	*	*
Nurses	*	* + some Sch 2		*	*	* including Sch 2-5 CD's	Full Formulary – Schedules 2-5 (iii)	Yes
Pharmacists (i)	*	* + some Sch 2		*	*	* including Sch 2-5 CD's	Full Formulary – Schedules 2-5 (iii)	Yes
Optometrists	*	*	*	*	* but not injectable medicines	No	No	No
Physiotherapists	*	*		*	*	* No mixing of CDs	List of 7 within Sch 2-5	No
Podiatrists	*	*	*	*	*	* No mixing of CDs	List of 4 within Sch 2-5	No
Therapeutic Radiographers	*	*		*	*	*	List of 4 within Sch 2-5 tbc	No
Diagnostic Radiographers	*	*		*				
Paramedics	*	*	*					
Dieticians	*	*		*				
Orthoptists	*	*	*					
SALTs and OT's	*	*						
Prosthetist	*	*						
Art, Music & DramaTherapists	*							
Psychologists	*							