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Information paper

The use of medicines with injection-therapy in physiotherapy services.

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Introduction

The use of medicines in physiotherapy injection-therapy settings has been common place for many years. In recent years, with the introduction of prescribing rights for physiotherapists, the mechanisms by which physiotherapists can access medicines has increased. In addition, the increasing provision of physiotherapy services by independent providers of healthcare has required a greater understanding of medicines frameworks in non-NHS settings.

In recent years, the issue of 'mixing' of medicines became a matter of intense professional debate, resulting in clarification of the law and substantive guidance on the matter from a range of national organisations, including the introduction of a CSP Information Paper PD003, which over the years has been through several versions to keep pace with changing clinical practice.

This 5th edition of PD003 aims to provide one common paper by which physiotherapists using injection therapy in any sector can reference for general information.

Members should read the following associated CSP Information Papers before reading this paper:

- PD019 – Medicines, Prescribing and Physiotherapy
- PD026 – Practice Guidance for Physiotherapist Supplementary and/or Independent Prescribers
- PD071 – CSP expectations of educational programmes in Injection Therapy

Members are reminded that at all times they are expected to work within the practice framework of the Health and Care Professions Council's (HCPC) Standards of Proficiency for Physiotherapists[1], The HCPC Standards of

Conduct, Performance and Ethics[2] , the CSP's Code of Professional Behaviours and Values[3] and the CSP's Quality Assurance Standards[4].

Section 1: Medicines Frameworks

Members must be clear as to which legal mechanism they are working within when they are injecting in order to practice in the appropriate manner:

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.

Mixing of Medicines

The Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for the enforcement of the Human Medicines Regulations 2012, which have superseded most parts of the Medicines Act 1968.

All medicinal products that are placed on the UK market must hold a marketing authorisation (product licence). There are exemptions from this requirement to allow for the supply or administration of unlicensed medicinal products. In brief, the exemptions apply to original products supplied to doctors, dentists or supplementary prescribers for the use of their named individual patients. The exemptions also apply to products specially prepared by a doctor or dentist or to his/her order for administration to patients.

Mixing two licensed medicines such as a local anaesthetic and a corticosteroid constitutes, under the terms of the Human Medicines Regulations, the manufacture of a **new unlicensed** product which therefore cannot be administered under a PGD. It is **not** the 'off-label' use of two must have licensed medicines. Local anaesthetic (LA) is not considered to be a vehicle for the administration of the corticosteroid, as the LA is not inert and has its own medicinal properties. The law now defines the term 'mixing' as

> "The combining of two or more medicinal products together for the purpose of administering them to meet the needs of a particular patient."

In physiotherapy practice mixing medicines can occur in a variety of clinical circumstances. Each medicine has its own medicinal properties and neither can be described as inert.

Members should be aware that mixing combinations of licensed medicines may be used in a wide range of clinical settings, but in each case where two medicinal products are mixed and one cannot be described as a vehicle for the other, a new unlicensed product is created and thus it cannot be administered under a PGD. Examples include:

- Musculoskeletal practice: LA and steroid
- Respiratory care: nebulised bronchodilator and antibiotic
- Women's health: antibiotic and antimuscarinic medicine

Mixing of medicines can occur under a PSD, supplementary prescribing, and nurse, pharmacist, physiotherapist, podiatrist independent prescribing. Mixing of medicines **cannot occur** within a PGD framework.

Insurance and Regulation

Injection therapy for therapeutic purposes is accepted as within the overall scope of physiotherapy practice. Since April 2011, members have been required to demonstrate that their education and training in injection therapy meets the standards set by the CSP in its publication PD071.

All registered physiotherapists are required by law to have appropriate insurance in place for their work. This may be provided by an employer, as benefit of a professional body membership, or purchased from an insurance provider.

Injection therapy used as part of physiotherapy practice is covered by the CSP PLI scheme for members, subject to the policy terms and conditions.

Section 2: Training in Injection Therapy

It is acknowledged that over time and with changing professional roles, there are examples of activities that have transferred from one professional group to another. Injection therapy is one example of this. Physiotherapists have performed this activity safely and effectively for many years and initially it was doctors who trained physiotherapists in the technique.

Doctors have the legal framework within which they may choose to use unlicensed products but most physiotherapists do not, with the exception of physiotherapist supplementary prescribers working within a CMP. Thus, when a skill is transferred from one professional group to another, due consideration needs to be given to the differing legal rights conferred upon each profession and each individual member of the profession by virtue of their own scope of practice. This may have an impact on the practical aspects of education and supervised practice in injection therapy.

The CSP has published expectations of educational programmes in injection therapy, and since April 2011 has expected all physiotherapists who wish to practice injection therapy to meet these educational standards[5].

As part of the competence training in injection therapy, members should ultimately be equipped with all the skills required to enable them to inject safely under the variety of legal frameworks available to them. Mixing the medicines in the syringe is a useful skill to acquire in that members may wish to use this technique when working under a PSD, or may in future be required to teach medical practitioners the variety of techniques in injection therapy. However, members must be clear that they must not use this technique if they will be working under a PGD, and that only HCPC annotated independent and/ or supplementary prescribers may mix medicines themselves prior to administration.

[5] PD071

Supervision provided by doctors under a PSD:

When a registered physiotherapist is being supervised by a doctor as part of their post-registration training process, the supply and administration of the medicines to patients comes under the framework of a PSD. However both the doctor and the physiotherapist will need to be clear which mechanism the physiotherapist will be injecting under once fully competent, i.e. PSD, PGD, supplementary or independent prescribing to ensure that appropriate knowledge, skill and competency is achieved.

Supervision by another appropriately skilled physiotherapist under a PGD:

The physiotherapist providing the training and support should be able to demonstrate that their own training meets the educational expectations as set out in PD026.

A physiotherapist independent and/or supplementary prescriber may prescribe the medicines required for injection therapy, and direct that the trainee-injector administer the medicines to the patient. Where the supervisor is not providing direct face to face supervision of the patient, the supervisor should follow CSP Practice Guidance for Prescribers guidance with regard to remote prescribing and/or prescribing on the recommendation of another health professional.

The law states that the supply and administration of medicines under a PGD cannot be delegated, thus the physiotherapist actually administering the injection to the patient must be named on the PGD. Therefore, when a registered physiotherapist is being supervised by another registered physiotherapist as part of their training process, **both** the trainee-injector and the supervisor **must** be named on the PGD document.

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.

This means the trainee-injector would need to be supervised by a doctor, other non-medical independent prescriber or physiotherapist independent and/or supplementary prescriber.

Where a trained injection-physiotherapist is asked to supervise another allied health professional using a PGD:

Where both professionals are employed by the same Trust and working to the same PGD there should no specific problems and the advice of the above section should be followed. However, in some circumstances e.g. rural settings with a scarcity of trained injectors, it may be that a supervisor for the trainee has to be sought from a different organisation.

Professional leads from both organisations should be aware of, and give authorisation to, the arrangement. This and the agreed competencies of the trainee should be detailed in the PGD. Local advice on this should be sought from the Clinical Governance Pharmacist. If it is not clear who the Clinical

Governance Pharmacist may be, the Chief Pharmacist should be approached in the first instance.

There would need to be a contract for the supervision arrangement and it should not be an ad-hoc arrangement. The formal arrangement should also include details of the clinical governance of the process. There needs to be discussion locally about accountability and injection-therapy training. If there is such a lack of skills for supervision of injection training in a given locality, it may need to be noted on the risk register of the employers in question. Both Trusts involved could consider sharing the content of their PGDs with each other to have some consistency of practice but there would still need to be separate clinical governance of each PGD by the respective Trusts. The pharmacists involved may be able to liaise with each other to discuss sharing content.

If the employer was unwilling to meet this requirement, then the trainee-injector would have to work under a Patient Specific Direction and thus by definition would need to be supervised by a doctor, other non-medical independent prescriber or physiotherapist independent and/or supplementary prescriber.

Where a trained injection-physiotherapist is asked to supervise a doctor:

In terms of competence, it is perfectly acceptable for a physiotherapist to be involved in teaching doctors injection-therapy techniques. However, the differences in the frameworks pertaining to prescription of medicines between the medical and physiotherapy professions mean there are several governance issues that could arise. Local advice should be sought from the Clinical Governance Pharmacist to explore the prescribing and supply administration issues and options. If it is not clear who the Clinical Governance Pharmacist may be, the Chief Pharmacist should be approached in the first instance.

It will be up to the discretion of the local Trust to consider the clinical governance issues and to ensure that trainee-injectors are appropriately supervised until such time as they demonstrate competence in performing the

technique autonomously. Clinical governance pathways and policies may vary between Trusts; however each physiotherapist performing injection therapy (either as a trainee or competent practitioner) has an obligation to understand the clinical governance issues pertaining to the medicines framework they are using , in particular PGDs, in force in their place of work.

Where a trained injection-physiotherapist (non-prescriber) is asked to supervise a physiotherapist who is a prescriber:

This will be similar to the arrangements for supervising a doctor, in that the trainee-injector is a prescriber, whilst the educator is not. A physiotherapist supplementary-prescriber may be able to prescribe the medicines required for injection therapy under the terms of the Clinical Management Plan in place for the patient. A physiotherapist independent prescriber will be able to prescribe autonomously. The supervisor will be supervising the injection technique, not the prescribing practice.

It will be up to the discretion of the local Trust to consider the clinical governance issues and to ensure that trainee-injectors are appropriately supervised until such time as they demonstrate competence in performing the technique autonomously

Section 3: Products used in Injection Therapy

Injection therapy for therapeutic purposes, whether in musculoskeletal or neurological settings, is already accepted as being within the overall scope of the physiotherapy profession. The medicines and/ or products that are used as part of injection therapy may evolve over time as may the techniques utilized to deliver therapeutic treatment parenterally. The CSP PLI scheme covers all activities that are within the scope of physiotherapy practice and injection therapy is accepted as within overall scope.

Products used in injection therapy may be classified as one of either 'medicine', 'device', 'blood or blood product'. Each of these categories is governed by law and members must be aware of the category of product they are using, and the relevant legislation that applies to the lawful and safe use of the product.

Techniques used to deliver parenteral intervention may include intra-muscular or intra-articular injections, cauda equina injections, IV administration, catheter administered preparations or syringe driver use. Members using any of these techniques must ensure that they are educated, trained and competent in the named technique in order to ensure that it falls within their personal scope of practice and competence.

3.1 Medicines

Adrenalin

Adrenalin is a POM and under normal circumstances must be prescribed by an appropriate practitioner. The Human Medicines Regulations makes specific provision for certain medicines to be administered by any person for the purpose of saving life in an emergency. The 18 listed medicines can be accessed and administered by any person should they be immediately available at the time of an emergency

Adrenalin 1:1000 up to 1mg IM for use in anaphylaxis may be administered to a patient, **if it is readily available**, without prescription, in a life threatening emergency. There is therefore no need for a formal medicines framework to be in place for the administration of adrenaline in a life-threatening emergency where a physiotherapist is employed by an organisation that has a formal written anaphylaxis policy in place, and the organisation provides adrenaline for use by its staff in the event of an emergency

If a life-threatening emergency occurs and the physiotherapist does not have ready access to adrenalin, e.g. on a crash trolley or other emergency box, they should follow basic life support procedures and call 999.

Should I have ready access to Adrenalin if I perform injection therapy?

Adrenalin may be administered in the event of anaphylaxis if it is readily available at the time of the emergency. In hospitals and other large organizations, adrenalin will be made 'readily available' in emergencies by being part of a crash trolley or other emergency/resuscitation bag. Members who work in other settings may not have ready access to such emergency supplies of medicines.

As a POM, physiotherapists cannot access supplies of adrenalin to hold for use in case of an emergency unless it is prescribed either on a named patient basis, or available under a PGD, or is supplied in some kind of emergency box.

For patients treated outside of settings that have crash trolleys and/or resuscitation bags it may not be practical or appropriate for adrenalin to be prescribed for each and every patient receiving injection therapy, given that the risk of such an event materializing is likely to be rare.

It will be for the individual clinician to decide whether they wish to offer injection therapy in the absence of having ready access to adrenalin. The decision will be based upon the clinical judgment of the clinician based upon the assessment of the patient and their medical history. Members will use a clinical reasoning technique to weigh up the risks and benefits of considering injecting without ready access to adrenalin, against the risks and benefits of alternative treatments or a decision not to inject.

In any event, as part of gaining the patients informed consent, the patient may wish to be informed of the risks of treatment and how any adverse event would be managed, and whether the clinician could offer treatment with

adrenalin or not. The patient may then give their own decision as to whether to proceed with an injection or not

Oxygen

Oxygen is legally classified as a General Sales List medicine but as a medical gas, there are stringent regulations concerning its supply to practitioners to ensure safe and appropriate use. Service providers are required to ensure that their healthcare professionals who administer oxygen are trained and competent to do so. In practice this means that physiotherapists may be required to use oxygen either under a PGD, or other local policy agreement that ensures robust standards for use of oxygen. Where physiotherapists travel between multiple sites for clinics, there should be a Trust policy on what is kept for use in emergencies by any health care professional on the site in question. Expecting a physiotherapist to carry oxygen around with him/her to their various clinic sites would not be appropriate.

The NHS Commissioning Board Special Health Authority (which has taken over the functions of the National Patient Safety Agency) provides guidance and supporting material on the safe use of oxygen in hospitals:
http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=62811&q=0%c2%acoxygen%c2%ac

Sodium Chloride 0.9%-for-Injection / Water-for-Injection.

All preparations for injection – whether inert or not - are classed as Prescription Only Medicines (POMs). Therefore where sodium chloride 0.9%-for-injection or water-for-injection is used as part of injection therapy their use must be within an appropriate medicines use framework.

Before mixing ANY product with an inert substance, such as water-for-injection or sodium chloride 0.9%-for-injection, the advice of a pharmacist should be sought to ascertain the pharmaceutical stability of the preparation and to assess any risks associated with the practice. If the manufacturer of a product does not refer to mixing/dilution of its product in its Summary of Product Characteristics (SPC) then this activity would be considered off label and in addition, may not be advised.

For example, if a corticosteroid (which is licensed) has a Summary of Product Characteristics (SPC) which states that it should not be mixed with any other substance, then mixing this product with sodium chloride 0.9%-for-injection would be an 'off-label' use of the corticosteroid, and would be permitted under PGD legislation as a new medicinal product is not created. However, this may not be safe practice as some products are not pharmaceutically stable when mixed together. Both the law and clinical issues have to be considered.

A further legal point to consider is that if a substance is diluted and the actual dose given to the patient then falls outside of the recommendations of the SPC then this falls into the definition of 'manufacture' i.e. you are creating an unlicensed product. Diluting a product to give a greater volume (but where the dose remains the same) may also not be within the licence of the product and would thus be off-label use of the product.

For example: 1mg of medicine X is the dose to be given to a patient:

If 1mg of medicine X is diluted in 10ml of product Y, and the full 10ml is administered to the patient, the dose has not been altered and 1mg has been administered. This is 'off-label' use.

If however, only 5ml of the diluted product is administered to the patient, then the dose has been reduced by 50% as only 0.5mg of medicine X has been administered. This is use of a new unlicensed product.

3.2 Devices

Some products used in the management of degenerative diseases have a 'physical' mode of action as opposed to a 'medicinal' action. Such products may include lubricants such as 'Ostenil'.

As such products are not classified as 'medicines' under medicines legislation, a written prescription is not required for their supply. However, manufacturer guidelines often stipulate that such products can only be supplied to registered health professionals and/or used under the direction of a doctor or registered health professional.

Whilst a legal written prescription is not required, good practice dictates that appropriate written policies and records are in place when such products are used.

3.3 Blood and Blood Products

Potentially using human blood as a product to achieve therapeutic effect via injection therapy is a further extension of the application of therapeutic injection therapy. The MHRA website provides information with regard to the various UK and European regulations that apply the use and/or handling of blood products www.mhra.gov.uk

3.4 Prolotherapy

This involves the injection of naturally irritant substances into joint spaces, ligaments and/or tendons, with a view to provoke inflammation to seek to promote healing.

Substances such as Lidocaine, Procaine, Dextrose (sugar) and/or saline may be used.

Where the substances used are classed as 'medicines', then they must only be prescribed, supplied and administered using an appropriate medicines framework.

Where the products used are not medicines, good practice dictates that appropriate written policies and records are in place when such products are used.

Members using prolotherapy as part of physiotherapy injection therapy practice must also consider the reasonable evidence base for the technique, and in particular if there is any specific guidance, such as NICE Guidance, that advises that the techniques are not recommended.

3.5 Cosmetic injectables:

At the current time, the use of all injectable products such as medicines and fillers, for cosmetic purposes, is outside the scope of physiotherapy practice, and thus outside of the cover provided by the CSP PLI scheme.

The prescribing of medicines for cosmetic purposes is outside the scope of physiotherapy prescribing and is not permitted.

Members who wish to build on their therapeutic injection therapy skills to develop into cosmetic treatments may do so, but must be fully aware that they are not acting as a physiotherapist, must not lead their clients to believe they are being treated by a physiotherapist, and must ensure that have alternative indemnity in place to cover this separate professional activity.

Section 4: Service Sectors

NHS

Injection therapy is well established within NHS services. There should be well established governance procedures in place to ensure appropriate medicines and clinical governance. All medicines frameworks available to physiotherapists are available in NHS settings, and the one selected will vary according to setting and service.

Independent Clinics (Private Practice)

Injection therapy is an accepted part of private physiotherapy practice. With health care reform, the independent sector is a growing provider of health services.

The Care Quality Commission (CQC) carries out the inspection of hospitals, care homes, primary medical services and mental health services. The type of organisation and activity that are required to be regulated are described in complex detail within *The Health & Social Care Act 2008 (Regulated Activities) Regulations 2010,* and the subsequent *The Health & Social Care Act 2008 (Regulated Activities)(Amendment) Regulations 2012.*

Not all professionals performing regulated activities are required to register with the CQC. Section 5 of Schedule 1 of the Regulations defines the health professionals that are included within the remit of these Regulations and physiotherapists are not listed. Therefore, whilst physiotherapists are clearly defined in law as health professionals, for the purposes CQC registration they are not required to register when offering services as a sole trader. Where a physiotherapist works in a partnership or organisation with other professionals, in setting subject to CQC registration, then there may be a requirement to register

Independent clinics which are registered with CQC are able to create their own PGDs for use with their private patients, subject to certain conditions being met. Independent clinics that provide services to NHS patients under formal written NHS contracts are also able to use NHS PGDs to treat the NHS patients treated under the contract.

Individual sole-trader private practice physiotherapists are exempt from CQC registration, and moreover would not meet CQC requirements for PGD creation. In this case, the only lawful mechanism for accessing the medicines required for injection therapy will be the PSD, supplementary and independent prescribing.

Working across NHS – private practice boundaries

If you are a private practice physiotherapist you will be **unable** to ask a GP to prescribe medicines for your private patients for you to administer in your private practice. This is because a GP is, by definition, a doctor who is contracted to provide primary medical services on the National Health Service to patients who sit within a defined **NHS** catchment population. GP's therefore prescribe NHS medicines which will be dispensed at NHS expense.

Prescribing medicines at NHS expense to be used in private practice may be theft and/or fraudulent use of NHS resources which may be subject to regulatory action if reported. Some GP's are also now unwilling to write private prescriptions for patients who are on their NHS lists, for medicines and services that are available on the NHS.

In order to access medicines in private practice, a solution is to establish a link with any doctor (i.e. a registered medical practitioner) who will be happy to write a private prescription (PSD) for your patient's, each of whom will subsequently have to pay for the full cost of the medicines i.e. cost of medicine, private prescription charge and dispensing costs.

Alternatively, if you are a supplementary prescriber you may work with a doctor who is willing to sign up to a CMP for each patient with you. This again is private prescribing and the patient is liable for the full costs of the medicines and associated costs.

If you prescribe as an independent prescriber in private practice this again is private prescribing and the patient is liable for the full costs of the medicines and associated costs.

Accessing supplies of medicines for private practice use

If you run a private practice you must consider how you will procure the medicines you need in order to offer injection therapy services. This may influence your business decision as to whether it is feasible for you to offer injection therapy services in private practice.

If you are an independent prescriber, you will be able to prescribe the medicines your patient needs. They can then obtain the medicines from a pharmacy and return for their injection.

If you are a supplementary prescriber, you must consider if you have a working partnership with a private doctor such that you are able to use a CMP to prescribe your medicines. This may be possible in larger multidisciplinary clinics, but may not be possible in small or single handed clinics.

PGDs can only be used in certain types of private clinic, e.g. those which are CQC registered or have a formal agreement to provide NHS services to patient in a private setting. If you work in a private setting where you cannot use a PGD, and you are not an independent prescriber, you must use a PSD.

If you cannot use any of the mechanisms above, you can only use a PSD. This means you will need to ask a private doctor to prescribe the medicines for your patients. The patient can then obtain the medicines from a pharmacy and return for their injection. They may agree to do this on your remote recommendation, but they may ask to see the patient, or decline to prescribe for your patient.

If you run a private practice you may be able to order some injection therapy supplies in bulk and store them on your premises:

- There are no legal restrictions on obtaining stocks of GSL medicines[6].
- For P medicines, you are allowed to receive stocks of any which are needed for the purpose of administration in the course of your business as a physiotherapist[7].

[6] Section 249 Human Medicines Regulations 2012
[7] Section 250 Human Medicines Regulations 2012

- You **cannot** order or receive stocks of POM[8] medicines under any circumstances. This means they must be prescribed as needed and then obtained via a dispensing pharmacist.

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[8] Section 249, Schedule 22 of Human Medicines Regulations 2012

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