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Medicines Management Policy

Incorporating Cold Chain Management

Version: 1

Name of originator / author:

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## 1. Introduction & Scope

The purpose of this document is to support the Safe and Secure handling of Medicines including management of cold chain. This policy related to Independent Prescribing as Patient Group Directives (PGD) or Patient Specific Directives (PSD) are not used within Skin Solutions Aesthetic Clinic Ltd.

The policy is underpinned by key legislation, for example, the Medicines Act, the Misuse of Drugs Act and associated regulations, the Health and Safety at Work Act, the Control of Substances Hazardous to Health Regulations and the regulations relating to the disposal of hazardous and other controlled wastes.

It is recognised that whilst individuals have a duty to ensure that medicines are handled safely and securely, the Organisation also has statutory responsibilities and a duty of care to staff and patients.

The term ‘medicines’ is used throughout the document as a generic term that covers all products administered by mouth, applied to the body, or introduced into the body

## 2. Initiation of treatment / Prescribing

A patient’s treatment must be initiated through a formal process which includes a consultation.

Other than adrenaline for use in an emergency situation and covered under the anaphylaxis policy, no stock of any prescription only medication is held on site to comply with legislation for nurses.

Prescription only medication (POM) eg botulinum toxin is held on site in a lockable metal cabinet complying to BS 2881 or within a lockable fridge, after completing a face-to-face consultation and is for use only on the patient noted on the medication label. Prescribing of POM is completed by e-prescribing through a registered and regulated pharmacist. A copy of the prescription is available and auditable on the prescriber’s pharmacy account.

Good practice principles in relation to prescribing (in line with current BNF guidance) should be followed eg:

*The strength or quantity should be stated by the prescriber.*

*The strength of liquid preparations should be clearly stated*

*The quantity to be supplied may be stated by indicating the number of days of treatment required*

*Due regard should be taken of any known allergies/hypersensitivity to medicines*

For computer-issued prescriptions the recommendations of the Joint GP Information Technology Committee should also be noted. Reference should be made to page 5 of the BNF (BNF 78).

Supplementary / Independent prescribers must only prescribe within their scope of practice and competency

In line with national guidance, including that of the GMC, where possible, you must not prescribe for yourself or those close to you

Independent prescribers are able to issue private prescriptions providing there is a clear audit trail.

**3. SSACLtd prescriber**

The director is a Registered Healthcare Professional who has successfully completed an appropriate nationally recognised prescribing course and is registered with their professional body as a person qualified to prescribe The prescribing of Prescription Only Medicines is restricted by the Human Medicines Regulations 2012 (and Controlled Drugs legislation), and the specific prescriber’s regulatory and professional body.

## 4. Unlicensed/Off Label Medicines

Unlicensed and off-label medicines (i.e. using a medicine outside of its approved use in the UK) may be prescribed by medical prescribers; however licensed medication should be used in preference. When using unlicensed medications, responsibility for the use of these rests with the prescriber, who remains professionally accountable for their judgement. The prescriber should inform the patient that the product does not have a marketing authorisation. or is being outside of its approved use in the UK

## 5. Dispensing

Transferring medicines from one container to another (i.e. split boxes) denotes dispensing and requires an agreed medical or pharmaceutical contractual framework

## 6. Ordering and receipt

The director of SSACLtd will order POM for named patients (not for stock) using e-prescribing from a pharmacy they have registered with.

On receipt of the medicines, the supply should be checked and any discrepancies reported to the pharmacy.

Some products require additional quality checks to ensure, for example, that the storage requirements through the ‘cold chain’ have been maintained.

**7. Controlled Drugs**

No controlled drugs are used or prescribed within the clinic

## 8. Secure Handling of Prescription Stationery

No prescription stationery is held on site.

### 9. Home visits

No home visits/prescriptions

## 10. Storage of medicines

SSACLtd will store medicines at a level of security appropriate to their proposed use in their original containers with Patient Information Leaflet so that they retain their batch number and expiry date. The packaging also protects the product from light and storage should be according to manufacturers’ recommendations. Failure to do so can invalidate the expiry date and cause manufacturers to disclaim responsibility for any apparent failure of the medicine, as the safety and efficacy of such medicines can be significantly compromised.

All medicines, with the exception of medicines for emergency use and wound care products, must be stored in lockable cupboards, which comply with the current British Standards for Medicines Storage (BS 2881), at a temperature not exceeding 25oC.

Refrigerated medicines must be stored at 2-8ºC and f**ridge monitoring must be completed recording both the current, minimum and maximum temperatures. Any deviation outside of normal range must be checked with the manufacturer before use.**

Medicines that are for internal use (e.g. oral, injectables) and medicines for external use (medicated dressings, topicals) should be stored in different medicines cupboards or different parts of the cupboard, on labelled shelves.

Access to the cupboards is restricted to authorised staff only

The location of the medicine cupboards is in a locked room in a locked building away from heat sources. Also, there is a minimal supply of POM on site at any time, regular stock checks are completed and a monthly audit completed. The ambient room temperature is maintained and patients are not left alone in the treatment room.

**11. Emergency drug Kit**

Once an emergency drug kit has been used it should be checked and missing items replaced as soon as possible. There is a system of checks in place for emergency kits that are assembled and stored ready for use, to ensure that they are complete and any medicine included is correct and within its expiry date.

Regular expiry dates checks should be carried out for all stock of non POM and stock checks completed and audited.

### 12. Ambient Room temperature monitoring

The ambient temperature of any room used to store medicines outside of a refrigerator must be monitored and recorded at least once daily using a maximum/minimum thermometer. This should be documented on the temperature recording sheet daily. Where the ambient clinic room temperature is at risk of exceeding 25°C, action should be taken locally to reduce this by e.g. removing any heat sources, or implementing an air-cooling device

A digital data logger must be implemented and will give additional evidence, and aid

tracking of probable causes of spikes in temperatures, especially when the area is not in use (e.g.weekends). This should be downloaded weekly (minimum frequency), and information stored locally.

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### 13. Storage of refrigerated medicines / Cold chain

**Pharmaceutical fridges**

A pharmaceutical refrigerators is available that is specially designed for the storage of medicinal / cosmetic products only and their use is required for all products requiring storage between 2°C and 8°C.

The refrigerator is be capable of maintaining the temperature of its contents between 2°C and 8°C with the minimum of intervention. Temperature monitoring should be by electronic max/min thermometer, with an accuracy of + 0.5°C, which should where possible be readable from outside the refrigerator. The data logger should be placed within the load to record the load rather than the air temperature, and the max/min temperatures should be recorded daily.

Due to products only being help for specific patient use and not stock, it is unlikely that the fridge will reach capacity. However,

* The refrigerator must be located inside a locked room
* Open the fridge as infrequently as necessary.
* The fridge must not be overfilled - allow space around the packaging for air to circulate.
* The fridge must be maintained and regularly defrosted (if not self-defrosting) in line with the manufacturers’ guidelines. Ice should not be allowed to build up as this reduces effectiveness
* As a minimum the fridge should be serviced annually and the temperature gauge calibrated
* Accidental interruption of the electricity supply must be prevented by using a hardwired socket.
* Medicines should be stored in their original containers so that they retain their batch number and expiry date. The packaging also protects the product from light.

Medicines that have experienced a cold chain excursion may remain stable for a limited period (or even until the manufacturer’s expiry date). A decision will need to be made on a case-by-case basis using information concerning the product, time out of the cold chain and the storage environment details i.e. temperature range. The above will vary depending on the medicine and therefore this information must be ascertained with the manufacturer or information leaflet before returning any medicines back into the refrigerator or discarding the medication.

### 14. Custody and safe keeping of keys

Keys will be kept securely in key cupboards with restricted access

## 15. Administration

No person should administer any medicine unless they are competent to do so and are acting within their sphere of professional practice.

Medication must be prepared for administration at the time it is due to be given. Medication for multiple patients must not be prepared in advance.

All aspects of patient consent should be considered

Any dose prepared for administration and subsequently not given should be destroyed.

Medicines shall not be returned to the container from which they were taken.

### 16 Remote prescribing

Remote prescribing is described as prescribing by an independent prescriber who authorises administration of a medicine to a patient without face-to-face assessment which must not be at the expense of safe and effective care and the prescriber must be satisfied they can make an adequate prescribing assessment; having adequate knowledge of the patient’s health, and are satisfied that the medicines serve the patient’s needs.

Remote consultations and prescribing provided online, over video-link or by phone can benefit patients, however, there are potential patient safety risks. Prescribers must be aware of these risks and be clear about their responsibilities for protecting patients and in respect of aesthetic treatments such as botulinum toxin, it is a requirement that a face-to-face consultation is undertaken prior to prescribing this medication.

## 17. Use of Injectable medicines

Within SSACLtd, some POM and other products used are given by injection. Some are already mixed but some require reconstituting and in this case a reconstitution or dilution agent eg bacteriostat or normal saline will be used

## 15. Return and Disposal of Unwanted Medicines

Medicines that are no longer to be administered to a patient, for whatever reason, should be returned to the relevant community pharmacy or dispensing doctor for disposal.

Medicines that have been issued directly to a patient should not be reused.

The storage, carriage and consignment of waste are all subject to stringent controls via Environmental, Waste, Transport and Health and Safety legislation.

The waste medicines should be deposited in a rigid medicine’s container; purple lidded sharps bins are used in SSACLtd

**16. Administration Errors**

If there is any risk of harm to an individual due to an incident involving medicines; priority must be given to the clinical care of that person(s). Duty of Candour applies along with an investigation is needed; refer to serious incident policy

### 17. Adverse reactions to drugs

If any patient experiences an adverse drug reaction (ADR), action must be taken to remedy any resulting harm caused by the reaction. The reaction must be recorded in the patient notes and the prescriber should be notified. A report of suspected adverse reactions should be made via the yellow card notification to the Medicines and Healthcare products Regulatory Agency (MHRA) on tthe following link [http://www.yellowcard.gov.uk](http://www.yellowcard.gov.uk/)

### 18. Spillage

Reference should be made to local policy and COSHH which should outline all cleaning requirements when dealing with spillage.

Initially the spillage should be soaked up with paper towels. Appropriate personal protective equipment (PPE) should always be worn. Care should be taken to avoid puncture wounds from associated glass or needles.

 

