JCCP Guidance Statement – Responsible Prescribing for Cosmetic Procedures.

Background

The recent aesthetic sector licencing amendment contained within the Health and Care Act (2022) and the enactment of the Botulinum Toxins and Cosmetic Fillers (Children) Act (2021) have caused prescribing in cosmetic procedures to come under close scrutiny. Discussions in both Houses of the Lords and Commons have been openly critical with regard to standards of prescribing for cosmetic procedures, presenting clear implications for professional and industry credibility and for patient safety.

Competence to prescribe is founded on an individual's professional qualification, advanced knowledge and their self-declared ability to work within their area of competence and expertise. This is a mechanism that has proven to be particularly effective where practitioners work within a system of oversight. In most circumstances, prescribers work closely with their peers whilst benefiting from national and/or local guidance and standards with which they must all comply. This combination of competence, professional regulatory control and guidance and local working guidance and standards, combined with the oversight of peer working provides a robust mechanism for patient safety and for enforcement and remediation when errors occur.

By contrast, the cosmetic sector is unusual in that prescribers usually work independently and without immediate oversight, frequently compounded by the commercial environment in which they work. Under these conditions there is a tendency for transparency of practice to be opaque, making enforcement by professional regulators and others more difficult. Examples could include situations when a prescriber fails to discuss the implications of using a medicine that is unlicensed or off-label with the patient, where they omit to provide appropriate directions for the use of the medicine or where there is absence of discussion with the patient or the person to whom the prescriber delegates treatment concerning the conditions that relate to remote prescribing, in an environment where such practice is less likely to be challenged.

This guidance document is prepared with this lack of oversight and local guidance in mind, but also with the understanding that the Government's new proposed licensing regime may act as a vehicle to close that gap and enhance regulatory compliance. The guidance presented in this paper concerns all non-surgical cosmetic procedures that are either cosmetic, medical or medically related in nature. Readers may be interested to review the JCCP paper 'What constitutes a medical, medically related or cosmetic procedure?',

The following document draws on the JCCP's experience of reviewing and responding to prescribing concerns, many of which are often fundamental in nature, and draws upon underpinning legislation as a starting point and aims to provide practitioners with guidance to assist them to perform their prescribing duties lawfully, safely and effectively.

Application of this Guidance

At the heart of this guidance is the principle of applying safe, ethical and legal practice with respect to the prescribing, supply and administration of prescription only medicines. To that end, reference is made to 'best practice' recommendations that the JCCP and its associated Clinical Advisory Group endorse for the benefit of responsible prescribers who operate in the aesthetic sector. However, the core of the guidance concerns the legislation which underpins prescribing practice, along with the guidance of the healthcare statutory professional regulators. From a legal perspective the JCCP considers that all persons using prescription only medicines in the cosmetic setting must at all times comply with legislation and with the requirements of their professional regulators if they wish to avoid the challenge of either criminal or fitness to practice notification. All prescribers are subject to professional regulatory requirements and as such must ensure that they prescribe in accordance with the guidance set down by their professional regulatory body and fitness to practice determinants. In accordance with these tenets the guidance set down in this document should therefore be regarded as a statement of requirement that is relevant to all prescribers and to all those, regulated or otherwise, with an interest in the administration of prescription only medicines.

The legislation that determines and restricts the supply and administration of medicines of all types is the Human Medicines Regulations (2012), enforced by the Medicines and Healthcare Regulatory Agency. This guidance has been reviewed by the MHRA who have determined its accuracy. There are numerous parts of this legislation that are relevant to cosmetic practice, but attention is drawn specifically to the following statement, taken from section 214 of this legislation:

> *A person may not parenterally administer a prescription only medicine unless the person is -*
>
> *(b) acting in accordance with the directions of an appropriate practitioner* [prescriber].

Remote Prescribing

Legislation does not provide a requirement to the legal enforcement of face to face consultations, however, in line with the guidance set down by several Professional Statutory Regulators (the General Medical Council and the General Dental Council and in accordance with guidance set down by the Royal Pharmaceutical Society) the JCCP and the CPSA (The Cosmetic Practice Standards Authority) have set down their decision not to endorse or permit the remote prescribing of any injectable prescription medicine and medical device when used for non-surgical cosmetic procedures. When the prescriber delegates the procedure to other practitioners, then the JCCP reminds the prescriber that the duty of care for the patient remains with the prescriber and the decision to prescribe must be compliant with the MHRA regulations and the Professional Statutory Regulatory Body guidance on remote prescribing. For the avoidance of doubt this guidance applies to the routine/planned administration of medicines or medical devices which are used for non-surgical cosmetic procedures, such as but not limited to, botulinum toxins, injected local anaesthetic, dermal fillers, hyaluronidase, tissue stimulants, vitamin infusions and injections, and agents used for lipolysis. Prescribers must not therefore prescribe such injectable medicines and devices for non-surgical cosmetic use by telephone, video link, online, at the request of others, for patients whom they have not examined personally 'face-to-face'.

Anytime that a designated Prescriber prescribes medicines or treatments, they must exercise their professional and clinical judgement, have adequate knowledge of the patient's physical and

psychological health status and be satisfied the prescribed medication best serves the person's clinical needs.

The JCCP recognises the important role that technology will play increasingly in the effective and efficient delivery of effective and productive prescribing and is cognisant of the need to ensure that the JCCP and the Professional Statutory Healthcare Regulators work together (wherever possible) to make sure that our approaches to regulation do not become barriers to innovation.

The JCCP has shared this statement with the professional regulators prior to publication. The Royal Pharmaceutical Society has also advised that '*In our view as the professional body for pharmacy, the JCCP statement is consistent with the approach of the professional regulators and will be useful for the RPS to signpost to".*

Delegation

Having prescribed a prescription only medicine, the prescriber may then delegate the administration of the medicine to a responsible and competent person. When delegating, the JCCP supports the position by some regulators which recommends that wherever possible non-surgical cosmetic procedures are delegated to a PSRB regulated practitioner but recognises also that prescribers may delegate the use of prescription only medicines for use by non-PSRB registered practitioners. We would remind prescribing practitioners that, if they do delegate, they retain an overarching and ongoing responsibility to the patient, including assessment of outcomes and intervention in and reporting of adverse incidents, both physical and psychological. Further, they must be satisfied that the person to whom they delegate is both competent and proficient to administer the medication prior to agreeing to prescribe any prescription only medicine.

There is significant anecdotal evidence, informed by requests received by the JCCP for advice, that some practitioners to whom the administration of a prescription only medicine is delegated are unable to determine the final dose, after reconstitution, of a medicine for parenteral administration. Therefore, evidence of the possession of requisite 'numeracy and literacy' skills to determine the dose at a given dilution, such that they can meet the directions of the prescription is necessary to ensure the safe administration of the medicine. Failure to demonstrate such competence could contravene legislation.

When the prescriber delegates the procedure after a face-to-face consultation, the JCCP purports also that the prescriber must be satisfied that it is safe to do so according to the client's physical and psychological history and in all aspects of safe administration, safe premises, safe storage of medicines/products etc, and reminds prescribers that if delegating to a non-registered practitioner the legal and professional liability for the delegation of the use of the medicine remains with the prescriber. The prescribing practitioner therefore accepts, in these circumstances, responsibility not only for oversight of the patient but also for the medicines they prescribe and for their subsequent use in accordance with expected professional practice and in accordance with appropriate legal parameters.

Supply of Prescription Medicines

If after a consultation a prescription is to be issued for *any* injectable prescription only medicine, this medicine may then be dispensed by a pharmacy. In these circumstances the purpose of this prescription is usually for the *supply* of the medicine only and is not commonly indicative of the treatment or dose required by the patient.

The JCCP is aware that it is commonly considered normal practice to supply parenteral medicines via a private prescription without the provision of any further patient direction. The effect of prescribing in this way is to facilitate autonomy, enabling the person delegated to determine for themselves the

dose required for the individual patient. The law makes it clear that 'direction' is a key element of prescribing. However, the consequence of this form of cosmetic practice may sometimes be problematic regarding patient welfare, professional standards and legal compliance. Therefore, the JCCP reminds prescribers that a **Patient Specific Direction** (PSD) is a legal method of prescribing and that, particularly when delegating, a PSD must be provided, and the procedure undertaken in accordance with it. JCCP would expect to see a PSD to include, at a minimum:

- Name of patient and/or other individual patient identifiers
- Name, form and strength of medicine (generic or brand name where appropriate)
- Route of administration
- Dose (per facial area for complex treatments such as botulinum toxin)
- Date
- Signature of prescriber.

Prescribers and practitioners may find the following statements and resources to be of use with regard to PSD's:

> 'Legislation states that all POM medications must have a written direction for administration and this has been confirmed by the MHRA'

Questions about Patient Specific Directions (PSD) – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice

Exemplar Scenario Relating to Delegation - Cosmetic Specific Guidance

After consulting with a patient, a prescriber prescribes 100 units of Botox®, completing a private prescription for issue to a pharmacy for the supply of the medicine. They delegate its administration to another person. The prescriber makes no further directions for the administration of the medicine.

In this scenario, the private prescription is the only direction available, that is, a direction to administer 100 units of Botox®. A direction must be specific to the named patient and appropriate for their needs. By contrast, the licensed dose for Botox® in treating all upper facial areas is 64 units, therefore the administration of 100 units would, in most cases, be considered significantly excessive and pose a risk of harm to the patient. The following are the regulatory and legal consequences.

- The prescriber's fitness to practice could be called into question.
- A regulated non-prescriber performing the procedure must request further written direction from the prescriber to avoid a potential fitness to practice challenge from their professional statutory regulatory body.
- An unregulated person performing the procedure should also request further written direction. Should they determine for themselves the required dose, they would be acting contrary to the direction and therefore contrary to the law.

All practitioners should note the requirement to discard the remaining product in accordance with the manufacturer's guidance and Health and Safety requirements.

Provision of 'Stock', Wholesale Dealing.

Doctors and dentists are eligible and permitted to hold a stock (i.e., where the medicines have not been dispensed by a pharmacist) of prescription medicines and are required to also complete a PSD when administering injectable medicines from this stock. In these circumstances the JCCP would remind such practitioners of their professional responsibilities when combining their roles of prescribing and dispensing. However, medical and dental practitioners are *not* permitted to provide advance stock of prescription medicines to others. Medicines legislation restricts the supply of medicines in this way through its provisions for wholesale dealing. The MHRA advise that the supply of medicines from stock is only permissible where the doctor/dentist delegates to a practitioner employed within the same employing organisation. The JCCP reminds doctors and dentists in these circumstances that they are accountable for the safe use and storage of these medicines.

The MHRA has advised nurse prescribers are not eligible to be supplied with prescription medicines as stock. In Scotland, Healthcare Improvement Scotland advise that 'w*ith regard to nurses and people operating registered independent clinics obtaining wholesale supplies of medicines (in Scotland), the legal position is that a nurse or a nurse independent prescriber cannot order and stock prescription only medicines (POM) or pharmacy medicines in their own right' and advise further that any "persons carrying on the business of an independent clinic" are able to order and stock prescription only and pharmacy medicines in connection with the running of the clinic. Furthermore, they advise that "If the service is registered with Healthcare Improvement Scotland you do not need to be a prescriber to order and hold stock. However, the practitioner must be a prescriber to prescribe from the stock allocation - this relates to all types of clinic, not just non-surgical aesthetic clinic*".

Requirement for Informed Consent

Informed consent is a fundamental ethical and legal tenet. It is a principle that is observed to ensure that an individual's autonomy is preserved, requiring that competent adults are made aware of and understand enough about the intended benefits and possible risks, including psychological risks, of the proposed procedure to enable them to make an informed decision.

- When prescribing or administering a medicine it is a requirement that the patient has the opportunity to give informed consent to this. To achieve this, you;
- must give patients the information they want or need to make a decision, and you should give them the time and support necessary for them to understand, retain and weigh up the information and use it to make a decision. Dialogue with patients is central to good decision making as you can find out what is important to them and identify the information, they will need to make a decision.
- must give patients clear, accurate and up-to-date information about the potential benefits and risks of harm of each option, including the option to take no action.
- should explore with patients what risks they would and wouldn't be prepared to take to achieve a desired outcome, and how the likelihood of a particular outcome might influence their choice.
- should try and reach a shared understanding of the expected outcomes and limitations of the [available options/medication to be prescribed or administered]

- Inform the patient of the details of the medication to be administered
- Inform the patient of the possible benefits and side effects of the medicine to be used
- Have sufficient information available for the patient to make an independent decision on whether they should decide to proceed with the treatment
- Inform the patient if you propose to use an unlicensed medicine and explain the reasons for your selection of the same
- Not mislead patients in any way, including with regard to any physical or psychological benefit or through reference to the nature of the medication proposed through inference or marketing. (For example…given the different characteristics of composition, diffusion, dosing and absorption for different toxins, informed consent would not have been deemed to have been correctly obtained if a patient had a reasonable expectation to receive AbobotulinumtoxinA (Azzalure) and was given NivobotulinumtoxinA (Innotox).

Repeat Prescribing

The JCCP does not consider an initial face to face consultation to have met the requirement for all future prescribing decisions. A cornerstone of prescribing practice is the requirement for shared decision making. If treatment is ongoing there should be clear arrangements in place to review decisions regularly, allowing patients the opportunity to ask questions and discuss any concerns. A follow up face to face consultation is therefore required at the discretion of the prescriber, but at a minimum whenever:

- A new medicine is prescribed
- There is a change to the dose of a previously prescribed medication
- There is a change to the medical history of the patient
- There is an adverse incident.
- More than 6 months have passed since the last consultation

When the prescriber is considering issuing a repeat prescription in the absence of a further face to face assessment of the patient, they must satisfy themselves that none of the above conditions apply and that mechanisms are in place to make an accurate assessment of these conditions.

Competing Interests

All prescribers must recognise and address the existence of competing interests. Practitioners should use their professional judgement to identify when conflicts of interest arise and avoid these wherever possible. When making a prescribing decision, practitioners must place the needs of the patient first and be transparent about their actions. Practitioners should declare any conflict to anyone affected, formally and as early as possible, in line with the policies of their employer or the organisation contracting their services. The approach to shared decision making with the patient concerned should allow for the psychological needs and signs of vulnerability to be considered and should not be influenced by personal gain or commercial interest. In support of this, the JCCP reminds all prescribers of their professional duty to abide by the Code of Practice set down by their Professional Statutory Regulator. The JCCP also recommends that the following ‘Nolan’ principles (adopted by the NHS in 1995 as the basis of the ethical standards expected of public service) should be adopted as an ethical framework for safe and ethical cosmetic prescribing practice:

- Selflessness
- Integrity
- Objectivity
- Accountability
- Openness
- Honesty
- Leadership

The JCCP accepts that prescribing for commercial gain is a necessary feature of cosmetic practise. However, prescribers must recognise any conflict of interest that is presented and take appropriate measures to manage these conflicts and to mitigate risk. All practitioners should be familiar with the guidance set down by their professional regulator in this regard - the following publication sets out the common position by all professional regulators. Joint Statement. Conflicts of Interest.

Prescribing in an Emergency

The JCCP accepts that where the requirement for a face-to-face consultation poses a risk of patient harm, for instance in the case of an emergency, then a remote prescription may in these situations be necessary. JCCP expect practitioners to comply with the requirement for a face-to-face consultation or to evidence in writing any deviation from it. Where the need for a remote prescription is found to be justified, the JCCP draw your attention to the following:

Practitioners must be familiar with the relevant legislation, stated elsewhere in this document, with regard to the provision of 'stock' through wholesale dealing, as contrary to medicines legislation.

Prescribers should be further familiar with legislation in regard to 'named patient' prescriptions and must not endorse the use of prescription medicines for a patient other than intended on the prescription.

A Patient Specific Directive remains a requirement in this situation and the direction must be appropriate for the nature of the presenting emergency at hand. The prescriber must ensure the competence of the practitioner who manages any emergency but as described above, this does not extend to permitting full autonomy with regard to clinical decision making. Where emergency medicines are supplied in advance of a potential emergency, it is expected that the prescriber will be informed immediately when an emergency occurs to confirm the prescriber's direction to administer a prescription only medicine, including its dose. The prescriber remains responsible at all times for the patient, including the assessment of outcomes and aftercare and, where necessary, the onwards referral for specialist expertise or to the patient's GP for information. The JCCP does not endorse any practice by prescribers that exposes patients to unsafe and potentially harmful outcomes. Examples of current unsafe and potentially harmful practice include:

- Prescribing for a named patient in quantities which facilitate 'stock' to be used for other patients.
- Prescribing in the absence of substantive and explicit direction which promotes a level of autonomous practice that is incompatible with the law
- Prescribing for practitioners who lack proven or tested competence.
- Failing to follow up, relinquishing responsibility for, and failing to advise in the management of adverse events and emergency interventions.
- Prescribing remotely with the primary interest of commercial gain and reducing the burden of responsibility for the prescriber.

The JCCP endorses the CPSA requirements for clinical oversight as best practice, which should in most instances avoid the need for remote prescribing in emergency scenarios. The JCCP considers that remote prescribing in an emergency situation should be regarded as a last resort rather than implemented as a matter of routine.

Offences

In addition to practising professionally and ethically to uphold patient safety and public protection, practitioners should also ensure that they adhere to the legal tenets that underpin prescribing practice in the United Kingdom.

All practitioners prescribing or administering prescription only medicines are reminded that UK legislation specifies the offences that are associated with contravention of the Human Medicines Regulations (2012). The Regulations consolidate the law of the United Kingdom concerning medicinal products and the prescribing of the same.

Section 255 of the Human Medicines Regulations outlines details of 'offences relating to dealings with medicinal products' and specifies that it is an offence against section 214 of the Regulations that 'administration otherwise than in accordance with the directions of a prescriber, is guilty of an offence punishable by a fine on conviction and up to 2 years imprisonment upon indictment'.

Further Guidance

The JCCP would refer Practitioners/Registrants to further guidance on Prescribing that has been published by their Professional Statutory Healthcare Regulators with specific acknowledgment that all regulators (both statutory and voluntary) advocate paramount responsibility for prescribing and promoting ethical and professional behaviours within the context of their 'Codes' and associated fitness to practise procedures. In particular the JCCP has considered and built on advice provided to Registrants by The General Medical Council, The General Dental Council, The Nursing and Midwifery Council, The General Pharmaceutical Council, The Health Care Professions Council and by the Royal Pharmaceutical Society.

Practitioners should read this document in conjunction with the JCCP statement previously released concerning the use and prescribing of unlicensed and off-label medicines.

Unlicensed medicines (1).pdf (jccp.org.uk)

Administering (or making arrangements to administer, including prescribing) botulinum toxins and dermal fillers to persons under the age of eighteen is now contrary to legislation unless used for medical purposes under the direction of a doctor. Prescribers should therefore be familiar with the relevant guidance:

Botulinum Toxins and Cosmetic Fillers (Children) Act (2021)

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