Cosmetic procedures: The supply of medicines to safeguard consumer health and wellbeing.

This document has been produced to inform members of the JCCP Clinical Advisory Group and national regulators, including the DHSC and is intended to address a long-standing concern expressed by non-medical independent prescribers and other organisations, including the Joint Council of Cosmetic Practitioners. It relates to the challenges faced by non-medical independent prescribers as they strive find the balance between assuring the safety of their patients whilst working within the confines of current legislatory restrictions when they are faced with urgent or emergency response scenarios. The JCCP is of the opinion that amendment is required to current legislation to enable non-medical independent prescribers to respond safely and effectively to emergency situations that might arise during clinical practice.

Rationale and Background

Instruments within the Human Medicines Regulations (2012) in England permit medical prescribers - doctors and dentists - to obtain prescription medicines on a 'wholesale' basis, that is, where the medicines have not been dispensed to a named patient by a pharmacist. This provides the medical prescriber with an immediate supply of a medicine from which they can prescribe and dispense or order the same to be carried out. It is a mechanism that facilitates appropriate patient access to medicines in a manner that is governed by the professional regulator. The medical prescriber is not permitted to pass on these wholesale supplies to others, but non-medical prescribers working within the same practice may access these medicines to prescribe and dispense. Again, this activity is governed by the relevant professional regulator.

An apparent anomaly arises where the 'independent' non-medical prescriber acts independently of their medical peers. In this scenario the non-medical prescriber has no immediate access to medicines since, for this group, allowance is not made for wholesale provision in legislation. They can supply them only through a prescription to be dispensed and they can authorise the administration through a patient specific direction. Where timely (and often immediate) access to emergency medicines is required to preserve a patient's health, the non-medical prescriber working independently is unable to access emergency medicines due to legal constraints . The non-medical prescriber typically perceives their professional obligations to include both working within the law and protecting or preventing harm to those in their charge in order to exercise their 'duty to care'. In the context of an emergency response scenario, it is this dichotomy that is the driving force behind all efforts made by practitioners to test the boundaries of current medicines legislation.

The following Government advice on these matters is now archived but the principle remains relevant.

> ***12. Can Nurse Independent Prescribers order and receive wholesale supplies of Botox® etc?***
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> *No. The law as it currently stands prohibits this activity and there is no intention to change this in the foreseeable future. The changes to legislation to introduce nurse independent prescribing were based on the long standing principle that a prescriber prescribes and that his/her prescription is then dispensed by a pharmacist. Nurse Independent Prescribers can administer drugs themselves and authorise others to do so under their patient specific*

direction. The Department of Health and the MHRA do not consider that there are compelling grounds for reviewing the position.

It is important to note that exemptions exist within the Human Medicines Regulations (2012) which permit specified professionals to be supplied wholesale 'stock' of specified prescription medicines, however, none of these exemptions apply to non-medical prescribers performing cosmetic procedures. Exemptions are also in place for the use of adrenaline in specified circumstances.

Health Education England qualifications framework for cosmetic procedures.

As part of efforts to address the findings of Sir Bruce Keogh in his review of the cosmetic sector, a key decision agreed and accepted by all stakeholders was the requirement for supervision and the primacy of the prescriber in that role. This was stated in recognition that consumer safety would likely be compromised in the absence of appropriate access to the medicines required to resolve adverse events, and that recourse to the NHS to meet that demand would be unacceptable. At that time it was noted that remediation of dermal filler induced complications would likely necessitate urgent attention through the provision and administration of prescription medicines. Following this, the Cosmetic Practice Standards Authority set out its supervision standards to include:

'For fillers it is a requirement that supervisors are able to be present within 15 minutes, as prompt delivery of hyalase (Level 7 prescriber) has a direct impact on the severity of injury in adverse incidents'.

Findings by the JCCP

Among some groups of cosmetic practitioners there exists an incomplete understanding of requirements set out in medicines legislation, a matter not improved by the inadequacies of current cosmetic education and training standards. Historically, the evidence received by the JCCP through expressions of concern has been anecdotal, although compelling in its volume. With regard to the use of medicines, both for emergencies and otherwise, the concerns expressed frequently point to either of two failings to adhere to legislation: the removal of dispensing labels with a view to providing the medicine to alternative customers, or the active prescribing for one individual with the encouragement to use the medicine for alternative individuals. This latter appears, for emergency medicines, to be more commonly promoted. Contrary to professional guidance, many medicines used in cosmetic procedures are prescribed remotely, where the practitioner has had sight only of the patient's notes. Invariably also, the administration of the medicine is not authorised through a patient specific direction. Therefore currently, the supply to and use of emergency medicines by non-prescribers is frequently:

- Prescribed for an individual (often the practitioner) with the tacit agreement that it can be used on any individual as required.
- Prescribed through a mechanism where the prescriber has not at any point had sight of the patient.
- Administered in the emergency situation without recourse to the prescriber and without the necessary authorisation or direction to do so.

More recently the JCCPs experience through the findings of regional Environmental Health Officer investigations has invariably served to corroborate the anecdotal evidence cited above. Furthermore, where the JCCP receive requests for advice from these Officers regarding the use of emergency medicine 'kits', the JCCP can only advise that it would be contrary to the law to possess them as stock items, something which comes as a surprise to these Officers, for whom public safety is their remit.

Most recently, information shared with the Medicines Regulatory Group in Northern Ireland finds that, from their investigations, this Authority shares the same experiences in that Devolved Administration.

It remains the JCCP's intention to work with the General Pharmaceutical Council where we see medicines being promoted or supplied inappropriately by its registrant pharmacies. The JCCP is aware that a number of pharmacies supply emergency kits on a prescription only basis, further reinforcing the JCCP's view that emergency medicines are promoted for inappropriate use. An emergency kit is by its nature something to be used with a named/designated individual in the event of an emergency. To supply it for this implied purpose but to require its prescription for a named patient is, at best, contradictory.

Emergency Kit | Ask Aesthetics

Emergency Dissolving Kit – Including POM Medication | Elite Direct Pharma

The JCCP continues to work with the MHRA to these same ends. We note that pharmacies have attempted to address the problem of emergency supply of medicines to 'dissolve' dermal fillers by obtaining what appear to be non-prescription alternatives. However, investigation reveals that this is at variance to the MHRA's opinion.

Dermaqual Disolvidase 1500 I.U. vials (askaesthetics.co.uk)

These efforts to assure safe and legal practise can pose the same contradiction for the JCCP and its stakeholders, including the Aesthetic Complications Expert group and insurance providers, as that experienced by non-medical prescribers. In the absence of alternative mechanisms, success in assuring legal practice can appear to pose a risk to patient safety by preventing access to emergency medicines. However, we are also mindful that there are hazards in any scenario where the supply of medicines is contrary to legal determination.

Compliance

It is widely understood that the standard of prescribing for cosmetic procedures too frequently fails to meet the demands of legislation and the expectations set out by professional regulators, although the true extent of this failure to comply is perhaps less well understood, particularly given the lack of available data in the sector. It is the JCCP's understanding that, for regulated professionals, nurses form the largest part of the sector, however it is also our experience that inadequate prescribing is a common feature across all professional boundaries. The JCCP appreciates that extending the scope of practice for non-medical prescribers to enable them access to specified wholesale medicines may be a cause for anxiety given the history of non-compliance. Nevertheless, a framework of licensing can offer important mechanisms of control and oversight aimed at remediating this practise.

Recommendations

It is a matter of priority to determine a mechanism which provides non-medical prescribers with access to a defined (to be determined) range of medicines for use in urgent situations to protect patient safety.

It is therefore recommended that regulators explore the potential for regulations within the framework of licensing, linked to exclusions within the Human Medicines Regulations, to enable the wholesale provision of these medicines to competent, licensed non-medical prescribers.

This measure will ensure that all non-medical prescribers, and those under their immediate supervision, will have access to the appropriate medicines in the emergency situation. It will not provide a solution for the patients of non-prescribers who are currently working independently. Further consideration, including that provided by the JCCP Clinical Advisory Group, should be given to this matter with a view to seeking options for resolution in the interests of patient safety and public protection. This could include further restrictions being introduced to limit independent practice for certain procedures performed by non-prescribers, something which would align with measures being considered by Health Improvement Scotland. The JCCP finds that current practices which undermine or seek to circumvent medicines legislation and professional credibility to be insupportable.

The JCCP Clinical Advisory Group (CAG)should explore options with a view to making recommendations for controls/safeguards to be introduced into a framework of licensing to ensure compliance with medicines legislation and professional standards of prescribing.

The CAG should consider the following to feature as part of such a safeguarding system of control. For the purposes of a premises license, or as part of a person/premises investigation, the Local Authority Environmental Health Officer should confirm that:

- Non-prescribing practitioners have a named prescriber to act as supervisor.
- All prescriptions provided by that supervisor, or any other prescriber, are set against a signed statement that they have been subject to a face-to-face patient consultation and assessment.
- All prescriptions should include an authorisation in the form of a Patient Specific Direction (PSD) recorded in the patient's notes.
- All PSD's include the prescribers name and PIN.
- No practitioner is in possession of wholesale stocks of medicines unless they are entitled to hold the same.
- Audit procedures are in place to enable the prescribed products to be traced from front end supplier to end point consumer.

The above list is indicative and should not be viewed as comprehensive. It should be informed by the published guidance provided by professional regulators for wider context. It does not account for the wider concern of responsible supply and procurement, that is, from the manufacturer, pharmacy or other source and this is the subject of other CAG project work.

The JCCP should continue to engage with the professional regulators to ensure that, as part of a scheme of licensing, they can support a mechanism of prescribing control that meets their individual and collective standards and requirements.

The JCCP CAG should make recommendations regarding the data capture that will be required to evidence the ongoing development of standards in this area.

The JCCP CAG should continue to work with the MHRA in its joint efforts to promote the reporting of adverse incidents.

The JCCP CAG should give consideration to a requirement for a publicly available national database of prescribing supervisors attached to non-prescribing practitioners/clinics.