Prescribing unlicensed medicines in cosmetic procedures

Botulinum Toxins

The JCCP has received a number of expressions of concern relating to the supply and prescribing of unlicensed botulinum toxins such as 'Botulax' from Korea. In response, the JCCP Clinical Advisory Group has reviewed the position of all relevant regulators with a view to outlining a common position as the basis for this statement. This paper has been subject to review by statutory regulators including MHRA, GMC and NMC.

It is within the remit of many prescribers to prescribe unlicensed medicines subject to certain conditions being met. Given what appears to be an increasing trend in the use of unlicensed botulinum toxins, the JCCP would remind prescribing practitioners of their responsibilities when prescribing in this way.

Unlicensed and off-license prescribing

To aid clarity it is useful to distinguish been off-license (off-label) and unlicensed medicines prescribing.

Unlicensed medicines are those that have not received a license (also known as a marketing authorisation) for use within the UK. Such medicines may or may not have a license for use in other countries. Botulax has a license for use in some countries but not in the UK and is therefore an unlicensed medicine.

"A licensed medicine meets acceptable standards of efficacy, safety, and quality".

MHRA: Off-label or unlicensed use of medicines: prescribers' responsibilities

Where a medicine receives a license for use within the UK, the license specifies the terms for the use of the medicine. Prescribing a licensed medicine outside of the terms of this license constitutes off-license prescribing. It is expected that prescribers should normally prescribe within the terms of the license. For cosmetic purposes, there are 3 brands of botulinum toxin that benefit from a UK license: Azzalure®, Bocouture® and Botox®. The terms of the license for these products include specified upper facial areas, and therefore prescribing treatment for, for instance, lower facial areas is off-license. Prescribing for the licensed indications of glabellar, forehead and/or crow's feet would constitute prescribing within the terms of the license only when all parameters are met, including within the specified age of the patient, the specified dose and subject to the outcome of assessment of the extent of the lines and their psychological impact. Prescribing for upper facial areas in the absence of these conditions is also off-license.

This statement concerns the use of unlicensed medicines and practitioners should note that the requirements for their use are set out in statute and apply to everyone. However, practitioners should also understand that additional obligations are set out in the standards expected by professional regulators when prescribing 'off-label'. As such we recommend that prescribers are familiar with and comply with their respective professional regulator guidance. For all prescribers, when prescribing off-label, consideration should be given to documenting the rationale for the prescribing decision, including its evidence base and confirming that this has been discussed with the patient.

Regulation

The MHRA is responsible for the oversight and enforcement of medicines legislation (Human Medicines Regulations (2012)).

Medicines legislation specifies exemptions which permit the use of unlicensed medicines to meet the individual patient's 'special needs', and such medicines are therefore sometimes known as 'specials'.

> 2.2 An unlicensed medicinal product may only be supplied in order to meet the special needs of an individual patient. An unlicensed medicinal product should not be supplied where an equivalent licensed medicinal product can meet the special needs of the patient. Responsibility for deciding whether an individual patient has "special needs" which a licensed product cannot meet should be a matter for the doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber responsible for the patient's care. Examples of "special needs" include an intolerance or allergy to a particular ingredient, or an inability to ingest solid oral dosage forms. These examples are not exhaustive.
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> 2.3 The requirement for a "special need" relates to the special clinical needs of the individual patient. It does not include reasons of cost, convenience, or operational needs. Anyone supplying an unlicensed medicinal product, where an equivalent licensed medicinal product is available must be satisfied as to the existence of a special need for the unlicensed medicinal product. MHRA expects that documentary evidence of this special need should be obtained by manufacturers, importers, or distributors and that this evidence should be made available on request of the Licensing Authority. This may take the form of a prescriber's letter, however an alternative fully documented audit trail through the supply chain confirming special need may be acceptable.
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> Supply unlicensed medicinal products (specials) - GOV.UK

Prescribers may also be interested to review their other responsibilities in section 8 of the above document.

Professional regulators, including GMC and NMC, are explicit in the requirements they expect of their members.

Doctors should be familiar with the GMC 'Good practice in prescribing and managing medicines and devices, (2021), paragraphs 104 to 109 and 'Guidance for doctors who offer cosmetic interventions'.

The GMC advise that:

- You should be satisfied that an alternative, licensed medicine would not meet the patient's needs before prescribing an unlicensed medicine
- before prescribing an unlicensed medicine or using a medicine off-label you should:
    - be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy

- take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up, or make sure that arrangements are in place for another suitable doctor to do so.
- record the medicine prescribed and, where common practice is not being followed, the reasons for prescribing an unlicensed medicine

You should usually prescribe licensed medicines in accordance with the terms of their licence. However, you may prescribe an unlicensed medicine where:

- On the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the patient's specific needs.

Where the decision is made to prescribe an unlicensed medicine and where that medicine does not follow common practice, you must further:

- Make a clear, accurate and legible record of your reasons for prescribing an unlicensed medicine

You must give patients, or their parents or carers, sufficient information about the medicines you propose to prescribe, to allow them to make an informed decision. And you must always answer questions from them about medicines fully and honestly.

If you intend to prescribe an unlicensed medicine where it's not routine or if there are suitably licensed alternatives available, you should explain this to the patient, and give your reasons for doing so.

The NMC position parallels that of other regulators and is equally clear in the guidance it provides to its registrants. Independent nurse prescribers can refer to the following document for confirmation of requirements for prescribing unlicensed medicines.

Nurse and midwife independent prescribing of unlicensed medicines (2010)

The GPhC has produced guidance for pharmacist prescribers which sets out the key areas pharmacist prescribers should consider when applying the standards for pharmacy professionals to their prescribing practice, including when prescribing unlicensed and off-label medicines.

JCCP Clinical Advisory Group

The JCCP CAG has reviewed the regulations, licensing status and industry specific factors concerning the use of botulinum toxins. They find no evidence that unlicensed versions offer any benefit over licensed alternatives and note that licensed brands are widely available. After consideration of professional regulatory requirements and the MHRA position broadly relating to commercial interests, CAG is unanimous in recommending this paper to the JCCP Board for wider dissemination to both prescribers and those to whom they delegate the procedure.

Summary

There are 3 brands of botulinum toxin available in the UK market that benefit from a license (marketing authorisation) for use in the UK.

There is no evidence that unlicensed brands offer any benefit that cannot be achieved with the currently available licensed brands.

There is and has been no lack of availability of licensed brands from authorised UK suppliers.

There is insufficient data for the safety and effectiveness in the UK market for unlicensed brands.

The use of unlicensed botulinum toxins is not common practice in the UK such that a reasonable consensus can be formed.

It is not acceptable to prescribe unlicensed medicines on the basis of any form of commercial interest.

Given the above, JCCP cannot support the prescribing, supply or in any way the use of unlicensed botulinum toxins. Where we receive a complaint concerning the prescribing of unlicensed botulinum toxins, we may refer the matter to the relevant professional regulator. This is particularly the case where the matter is aggravated by the lack of consent or understanding on the part of a patient or consumer who later finds they have received an unlicensed botulinum toxin.

JCCP will continue to work with MHRA and with pharmacy regulators to address inappropriate supply of unlicensed botulinum toxins and with insurance companies to highlight the implications on the validity of indemnity.

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-Ends-

Notes to Editors:

For general information and enquiries on the JCCP and a full version of the JCCP Guidelines on use of Social Media go to: **www.jccp.org.uk**

For further information on standards for non-surgical aesthetic treatments and hair restoration surgery please go to: **www.cosmeticstandards.org.uk**

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