



**THE USE AND
SUPPLY OF
TOPICAL
ANAESTHETICS.**

August 2023

Introduction

This guidance is aimed at those in the UK who use topical anaesthetic products as part of their practise to provide pain relief, including cosmetic practitioners, tattoo artists and body piercers. It should also serve as a guide for those responsible for the oversight of public safety, particularly Environmental Health Officers. The Joint Council of Cosmetic Practitioners has received numerous concerns relating to the use of these products and the objective of this guidance is to promote their safe use within the confines of medicines legislation.

Why is this important?

Topical anaesthetics, like all medicines, carry risk and those risks are minimised when they are used appropriately. Medicines legislation is designed to facilitate this. For instance, topical local anaesthetics pose a minimal risk of potentially fatal toxicity in ordinary circumstances, but this risk rises rapidly when they are used:

- In high doses
- Over large areas of the body
- Where the skin lacks integrity
- On certain areas of the body
- Under occlusion
- Where age or medical conditions limit the ability of the body to process the anaesthetic.

For some medicines, legislation controls the available dose with a view to minimising the risk. For others, the medicines can only be provided under the authorisation of a prescriber who can provide specific directions allowing for the other factors.

Medicines

UK medicines legislation (The Human Medicines Regulations (2012)) determines that medicines fall within one of three categories, for which they receive a license. These categories are:

- General Sale medicines are authorised medicines which are considered reasonably safe to be sold without the supervision of a pharmacist.
- Pharmacy medicines can only be supplied under the advice of a pharmacist, directly to the consumer or their nominated representative.
- Prescription medicines can only be supplied against a prescription from an appropriate professional.



The JCCP finds that products often arise, either for sale within the UK, online or purchased from abroad, that have not received a license. In these instances, the products are ‘unlicensed’ medicines. It is important to note that the safety, quality and efficacy of unlicensed medicines has not been established. Individuals who buy unlicensed medicines face an unknown risk and may be supplied with medicines that are not safe or suitable for them to use.

Unlicensed medicines can be supplied in specific circumstances, and they are subject to additional controls and can only be made available through a prescription. They must only be used where the prescriber identifies a specific need for a specified patient that cannot be met by a licensed alternative. It is relevant to note that non-prescription medicines may also be prescribed.

Types of local anaesthetic

Topical local anaesthetic products are used across a variety of health and non-healthcare sectors where there is a need to minimise the pain associated with the procedure. The product limits the sensation or 'numbs' the area to which it is applied. Outside of the healthcare setting these products are frequently found within the tattoo, beauty, and aesthetic sectors. The most common form used in these sectors is a cream, although these products are available in other formulations including sprays, gels, and patches. The products are sometimes applied 'under occlusion', where an airtight dressing is applied on top of the cream to aid absorption and increase effect.



The most commonly used legitimate topical local anaesthetics are 'Pharmacy' medicines. As licensed products they typically contain 5% or less active ingredient (for instance lidocaine) at quantities of 5g. This provides a total dosage of 250mg lidocaine which is considered to be within safe parameters. Licensed examples of these products are Emla® and LMX4®. Products in higher concentrations are typically prescription medicines and may or may not be licensed. Legitimate products sometimes consist of alternatives to lidocaine, including benzocaine, prilocaine and tetracaine, and others including Emla® contain a mixture of ingredients. Legitimate products are available in higher volumes including 30g tubes or multi-dose packs, however, these are not usually appropriate for use by a single consumer and should not be used on multiple consumers.

Environmental Health Officers should be aware that they may encounter local anaesthetic creams containing additional active ingredients such as corticosteroids (for instance lidocaine and hydrocortisone). These products are inappropriate for use in these non-healthcare settings. Further, local anaesthetic agents for injection are increasingly common, particularly in the aesthetic sector. These products always require a prescription and additional safeguards that are not within the remit of this guidance.



How to meet the requirements

Other than for certain practitioners such as doctors and dentists, Pharmacy medicines should only be purchased from a UK pharmacy. This means that the medicines have been imported appropriately and are safe to use within the terms of their license. Both practitioners and consumers are advised to read the 'pack insert' or Patient Information Leaflet which provides essential information about those terms. Importantly, a pharmacy will only supply medicines where it is safe to do so and only to those who are entitled to receive them. For practitioners this provides the additional assurance that they are working safely and within the law.

Unregulated or non-prescribing practitioners are not entitled to supply Pharmacy medicines directly to their clients. The JCCP advises that practitioners request their clients to procure, from a UK registered pharmacy, the appropriate product and apply it in advance of the procedure.

If a pharmacist does supply a pharmacy medicine to a practitioner for use on a client, it must be used only on that customer and according to the terms of any advice offered.

Alternatively, pharmacy supplied medicines or stronger prescription products may be supplied through a prescription and used for the named patient according to the specified directions of the prescriber.

Practitioners and responsible officers are advised that, unless there is evidence of a prescription, products of a strength greater than 5%

should not be made available to the public. Further, any product that is procured from outside of the UK, or from any online source that is not a registered pharmacy, is likely to breach the safeguards of medicines legislation.

In general terms, most clinics should not have routine access to any topical local anaesthetic product unless they can evidence:

- A prescription which demonstrates that the medicine was dispensed to a named individual, for use on that individual only, or
- That it was supplied by a registered UK pharmacy for a specified patient.

Where the product has been purchased online, the online source must be a registered pharmacy. The website should display the pharmacy registration number, and this should be confirmed as legitimate by checking against the entry on the **General Pharmaceutical Council Register**.

If medicines are supplied by individuals or organisations within the UK to persons not entitled to receive them, The JCCP advises reporting the matter to the **MHRA medicines enforcement**.

The JCCP also remind practitioners and consumers that adverse events associated with any medicine should be reported to the MHRA using the **Yellow Card Scheme**.

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