

Wrinkle free?



Greg McEwen looks at the regulations associated with Botox

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Increasingly people (predominantly women) are choosing to undergo 'anti-ageing' procedures to maintain a more youthful appearance. The options used to be limited to 'going under the knife' for a facelift. Few were willing to take such a dramatic step, which involved a long and potentially painful recovery. 'Non-surgical' cosmetic treatment has now become a growth area. Botox, chemical peels and dermal fillers all promise to reduce signs of ageing without the time, worry or expense of surgery. Increasingly these 'quick fixes' are offered not only in clinics and dental surgeries but also in beauty salons. Non-surgical cosmetic treatments are now relatively inexpensive and available on high streets. Having moved from the fringes into the mainstream, surely these treatments must be safe. Or are they?

In fact Botox (*botulinum A* toxin-haemagglutinin complex) is derived from *Clostridium botulinum*, the cause of botulism, and is one of the most powerful toxins known to man. Its ability to instil muscle paralysis was first harnessed by the medical profession to treat certain facial disorders, such as 'cross eyes' or uncontrolled blinking. Recently uses have broadened to include the treatment of wrinkles and the control of sweating. Despite this, the use of Botox in the UK for cosmetic treatments remains outside the product's licensed indications. Practitioners using it in this way therefore do so 'off-licence'.

These treatments are increasingly ubiquitous in the UK and it is a surprise that there is still little formal regulation of the non-surgical cosmetic industry. In comparison, surgical facelifts are performed in operating theatres by qualified doctors with years of training, who are registered with the General Medical Council and indemnified by their medical defence organisations. There are mandatory requirements to ensure the patient is operated on by professionals with minimum levels of expertise and experience and that they have adequate redress if something goes wrong. The position may be different if a patient opts for something apparently 'safer', such as Botox or fillers.

Regulation of non-surgical procedures originally came within the ambit of the Healthcare Commission (HCC). Since 1 April 2009 the HCC has ceased to exist and has been replaced in England by the Care Quality Commission (CQC), the new independent regulator of health and social care. The remit of the CQC is broad, touching upon everything from healthcare to social care and mental health services. In terms of non-surgical cosmetic treatment, the regulatory position did not change.

Essentially, only treatment involving surgery, lasers or intense pulsed light are formally regulated. Where there is no formal regulation (which applies to most non-surgical cosmetic procedures), registration with the CQC is not required.

The government has requested the Independent Healthcare Advisory Service (IHAS) to investigate and produce proposals for a self-regulating framework in respect of the cosmetic industry. According to IHAS:

Cosmetic treatments comprise non-surgical, non-incisional (although in some cases piercing of the skin may be involved) procedures that revise or change the appearance, colour, texture or structure of bodily features to achieve what patients perceive to be more desirable.

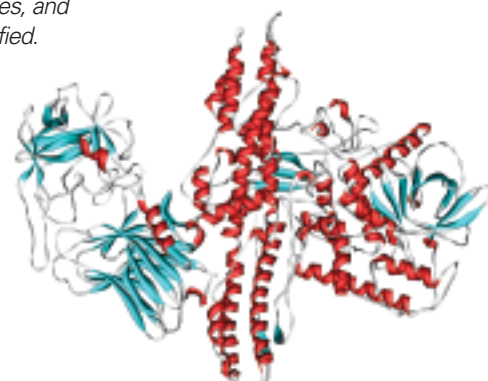
IHAS has to date produced guidance standards for injectable cosmetic treatments, including Botox and dermal fillers, which recognise that such treatments may in practice be provided by doctors, dentists or nurses. In addition, the individual professional bodies have in many cases issued their own broad guidance to members. The current guidance from the General Dental Council states:

Registrants choosing to offer Botox or other non-surgical cosmetic procedures should note that the GDC expects the same high standards of them, whatever the type of treatment they are carrying out. In particular, they are advised to work within their knowledge and professional competence and be prepared to back up the decisions they make. Careful thought also needs to be given to maintaining professional standards in relation to advertising these services, and the need to be indemnified.

The involvement of the Medicines and Healthcare products Regulatory Agency (MHRA) within this industry-wide self-regulating model is fairly limited. The MHRA administers the regulatory framework governing the supply and use of medicines, eg Botox is a prescription-only medicine. The MHRA can and has prosecuted individuals for offences under the *Medicines Act 1968*, including the illegal import, possession and supply of prescription-only medicines and the placing on the market of unlicensed medicines. For the purposes of the relevant regulations a dermal filler is not classed as a medicine and is in fact a 'medical device'. Regulation of those products is limited to the product meeting the appropriate European standard and qualifying for a European CE mark or 'kite mark'. Thereafter, it can be freely marketed within Europe. IHAS sought advice from the MHRA and was advised that it was not possible to designate dermal fillers as prescription-only medicines (in which case they would only be available for prescription by an appropriately qualified practitioner). According to the MHRA:

...you cannot use the Medical Devices Regulations/Directives to restrict the availability of a device as a means to control the service provider.

Faced with this advice, IHAS is exploring the development of a Code for Manufacturers. Currently development remains at an early stage and a variety of dermal fillers, both permanent and non-permanent, are widely used by providers, eg doctors, dentists, nurses etc.



3D ribbon model of botulinum neurotoxin serotype A (Botox)

In relation to 'injectable medicines', these will continue to be administered by a wide range of practitioners. The MHRA guidance confirms they can be administered by 'an appropriate practitioner', which may include a doctor, dentist, nurse or pharmacist. Such medicines can also be administered by others 'in accordance with the directions of an appropriate practitioner'. Consider a cosmetic clinic in which staff administer Botox under the direction of a resident doctor. There is no legal requirement for a face-to-face consultation between doctor and patient. Nor is there any legal requirement that the doctor's 'direction' be in writing.

In view of this, the Nursing and Midwifery Council (NMC) has issued guidance to nurses, stating that it is not considered good practice to administer medicines from a remote prescription or by remote direction.

The Department of Health has issued guidance for patients considering a non-surgical cosmetic procedure, designed to identify suitably qualified and competent practitioners.

Amongst the questions that would-be patients are advised to ask are:

- 1) Who will carry out the treatment?
- 2) How long have they been trained in this treatment and do they have a certificate of accreditation?
- 3) How frequently do they carry it out?
- 4) Do they have professional indemnity or insurance?
- 5) Is the treatment right for me?
- 6) How long does the treatment take?
- 7) Is the treatment painful and if so what form of anaesthetic is used?
- 8) Is all equipment used sterile and used only for me?
- 9) What are the risks involved?
- 10) Are there any other treatment options available for me to achieve the results I want?
- 11) What will happen if I am unhappy with any aspect of the treatment?

Inevitably, some patients will remain dissatisfied. The rapid growth in cosmetic treatments has a corresponding growth in related litigation which solicitors are handling alongside mainstream clinical negligence and personal injury work. At least one legal firm is advertising a dedicated department dealing solely with cases of alleged negligence in cosmetic cases.

The media is quick to report on cosmetic horror stories, particularly involving a 'celebrity'. Whilst many claims are of comparatively low value, this is no guarantee. Consider the 'high flyer' with a glittering career before them. It is not unprecedented for claimants to allege they have been left unable to work as a result of their 'disfigurement' and the corresponding claim for loss of earnings can be significant. Moreover, many cosmetic claims also include claims for psychiatric injury.

Increasingly, as people are opting to undergo cosmetic treatments, treatment providers need to ensure that they are complying fully with the current patchwork of regulation by ensuring they have in place adequate indemnity or insurance covering the full extent of their practice. If in any doubt, providers should contact their insurer or defence organisation. As this area of clinical practice continues to develop it seems that there will still be the odd 'wrinkle' to smooth out.

Non surgical cosmetic treatment

Dental Protection has recently announced that, with effect from April 2010, the use of injectable, non-permanent cosmetic procedures such as botulinum toxin and non-permanent dermal fillers in the face (but excluding the neck) can be indemnified within normal subscription categories at no additional cost, subject to certain conditions

This has been achieved by re-defining '*dento-alveolar procedures*' to include these non-surgical facial procedures. Previously, it was necessary either to transfer to a Dental Cosmetic category at significantly higher subscriptions, or to purchase a separate indemnity for these cosmetic procedures from a third party, and at an additional cost.

This change has been introduced to reflect three recent developments:

- 1) The completion of the promised detailed review of Dental Protection's claims experience from these procedures since the separate cosmetic and adjunctive categories and subscription rates were first introduced six years ago. This review has taken into account the medical (MPS) claims experience from these procedures over this same period and previously
- 2) The imminent launch of the Shared Regulation scheme agreed between the GMC, GDC and Nursing & Midwifery Council (NMC), and the Independent Healthcare Advisory Services (IHAS)

3) The imminent launch of the associated third party (voluntary) Registration and Inspection Scheme for providers of these procedures, incorporating the IHAS Quality Mark which is designed to demonstrate to patients and third parties that the provider has received appropriate training in the use of these procedures, and is committed to the Standards for Cosmetic Injectables under the auspices of IHAS - including the inspection of the facilities in which these procedures are to be provided. Caspe Healthcare Knowledge Systems (CHKS) is to be the third party registration, quality assurance and inspection agency.

The conditions under which these procedures can be indemnified by Dental Protection within normal subscription categories and rates are:

- the member must be registered with CHKS under the forthcoming IHAS scheme and possess the IHAS Quality Mark
- these procedures carried out in the immediate peri-oral area, nasolabial folds and elsewhere in the face are all included, but the neck is specifically excluded
- only non-permanent injectable cosmetic procedures are included
- these procedures, plus any other dento-alveolar surgical procedures (such as third molar removal, implant placement) must not collectively occupy more than 500 hours a year (10 hours per week on average). Where they do exceed this threshold, a further subscription category is available at an additional cost which is still less than the rate for the lowest Dental Cosmetic category.

The existing Dental Cosmetic categories remain available for

- a) those who wish to carry out these procedures but who are not yet registered under the voluntary IHAS scheme and who have not achieved the IHAS Quality Mark
- b) those who wish to use non-resorbable/permanent fillers and similar techniques
- c) those who wish to extend their indemnity to include other dento-facial cosmetic techniques such as dermabrasion, chemical facial peels, high energy wrinkle reduction therapy and any form of cosmetic laser technique.

Further information and a revised position statement is available via www.dentalprotection.org/uk/news/positionstatements