

# Guidance notes 4 (GN4): Hillingdon's position on advanced therapies

## Advice in relation to the use of advanced therapies

### Purpose

The purpose of this guidance note (GN4) is to support the Regulations applying to Massage and Special Treatments Premises [99KB] and the codes of practice prescribing standard conditions of licence adopted by the council in respect of special treatment establishments. This particular GN is concerned with advanced treatments and those that the council has determined are not licensable, as they are conducted only by medical practitioners or are regulated by other legislative agencies.

### Treatments by registered medical practitioners

All treatments conducted by registered medical practitioners (ie doctors registered in England and Wales by the General Medical Council) may carry out treatments without the need to be licensed.

### Health and Safety Enforcement

Although premises providing advanced treatments may not be deemed to fall within the definition of a special treatment establishment, and therefore do not require a licence from the local authority, this does not absolve those who carrying out the procedures from their absolute duties under health and safety.

Health and safety enforcement responsibility will usually be vested with the local authority, although in some cases the responsibility may lie with the Health and Safety Executive. Irrespective of the enforcement authority for health and safety, the same legal standards apply.

### Advanced treatments

Below is a list of treatments that the council has considered for licensing, together with a selection of frequently asked questions and answers.

#### Botox

Is this a special treatment under the London Local Authorities Act?

- No this is not a treatment under the Act. The reason for this is that the treatment involves the injection of a substance that requires medical prescription.

What does the treatment involve?

- The injection into/above the muscles of the face (or other parts of the body), to block the nervous impulses that pass through the muscle. This in effect makes the muscle relax, and should permit the ease of lines etc, caused by muscle contraction.

What is the substance/product used?

- Botox is a common term used for the substance derived from the botulinum toxin. This product is regulated by the Medicines Act 1968, and has the classification prescription only medicine (POM).



Who may legally provide this treatment?

- The classification POM restricts the use of botox only to a registered medical practitioner, or a person under the supervision and control of a registered medical practitioner. Beauty therapists cannot legally provide the treatment without the prescription of botox, and within a framework set and supervised by a medical practitioner.

Who is the health and safety enforcement authority?

- The Health and Safety Regulations allocate local authority enforcement in the case of cosmetic services, except where they are carried out under the supervision or control of a registered medical practitioner. Where the treatment is carried out at a clinic or surgery (premises) of a medical practitioner, the enforcing authority will be the Health and Safety Executive. However, where visiting practitioners (including doctors/nurses) attend the premises of a beauty therapist to provide the treatment, the enforcement will be assigned on the main activity concept and will thus remain the responsibility of the local authority.

Is this treatment regulated by the National Care Standards Commission?

- No, the Private Health and Voluntary Health Care (England) Regulations 2001/3968 removes subcutaneous injection(s) of substances for cosmetic purposes from the definition of listed services under the Care Standards Act 2000.

### **Mesotherapy**

Is this a special treatment under the London Local Authorities Act?

- We have determined that this treatment falls outside the definition of a special treatment, and will not be licensed.

What does the treatment involve?

- The injection into the muscle of a homeopathic substance often used for the treatment of cellulite in women. This is a common treatment on the continent.

What is the substance/product used?

- A homeopathic substance. Due to the nature of the substance used it does not require a product licence from the Medicines and Healthcare Products Regulatory Authority.

Who may legally provide this treatment?

- Anyone who is injecting a substance into another for the purpose of a beauty treatment is prescribing. In order to be considered competent in prescribing, a person must be able to fully explain, and respond to contra-indicators of the treatment. There is the possibility, as with all homeopathic substances for a person to be allergic to the treatment, and only premises equipped for dealing with acute allergic responses would be suitable (ie with a doctor in attendance).

Who is the health and safety enforcement authority?

- Where this treatment is carried on at the premises of a beauty therapist, and the main activity is not 'medically orientated' the enforcement authority will be the local authority. In all other cases (e.g. doctors surgeries) the treatment is the responsibility of the Health and Safety Executive.

Is this treatment regulated by the National Care Standards Commission?

- No, for the same reasons as botox (see above) this treatment appears to fall outside the regulation requirement.

### **Collagen/Hyaluronic acid injections/implants**

Is this a special treatment under the London Local Authorities Act?

- No, we do not consider this a special treatment, as in our opinion it falls outside the definition of special treatment allowed under the Act.

What does the treatment involve?

- The injection of product under the skin. This has the effect of filling, and is used in the beauty industry for wrinkle/facial lines correction, lip augmentation, and re-shaping the chin/cheeks/forehead. The treatment is not permanent.

What is the substance/product used?

- Collagen is a naturally occurring protein, derived from animal origin. The product may be synthesised and/or refined hyaluronic products are derived from an acid base, and acts in a similar way to collagen.

Who may legally provide this treatment?

- Products must be used in accordance with the product licence. Whilst not a medicine, and therefore not covered by the Medicines Act in terms of prescribing formulae restrictions, it is unlikely that anyone other than a qualified medical practitioner would be able to demonstrate the necessary knowledge and skills to provide this treatment. That said, there is no legal restriction on who can provide this treatment.

Who is the health and safety enforcement authority?

- As with the other treatments listed above, the enforcing authority will, be the responsibility of the local authority, unless the treatment is carried out in a private dwelling or at a premises where the main activity is carried out by a medical team.

Is this treatment regulated by the National Care Standards Commission?

- No, the Private Health and Voluntary Health Care (England) Regulations 2001 exempts subcutaneous injection of substances for cosmetic purposes, and fillers are likely to fall within this definition.

### **Laser/intense light-pulse**

Is this a special treatment under the London Local Authorities Act?

- These treatments do fall within the scope of the London Local Authorities Act (LLA) but at present there is a dual regulatory role with the National Care Standards Commission. This authority has therefore deemed that a licence under the LLA is not required.

What does the treatment involve?

- In the context of beauty/cosmetic treatments, this guidance refers to the use of the laser/intense pulsed light for hair removal (epilation). In essence, the

treatment introduces a radiation that causes damage to the hair-follicle.

What is the substance/product used?

- There is no regulated medicinal product used in this treatment. The risk from this treatment arises from the use of the laser/intense pulsed-light.

Who may legally provide this treatment?

- Persons who have received training and instruction in the use of the laser/intense pulsed-light, and who have demonstrated to the National Care Standards Agency that they meet the required safety and procedural standards.

Who is the health and safety enforcement authority?

- Where lasers/intense pulsed-light is used within beauty therapy establishments, health and safety enforcement in most circumstances will be the responsibility of the council. Exceptions to this rule will be where the treatments are carried out in the surgeries of medical practitioners, within hospitals etc.

Is this treatment regulated by the National Care Standards Commission?

- Yes, the Private Health and Voluntary Health Care (England) Regulations 2001 extends listed services under the Care Standards Act 2000.

### **Red vein treatments by injection**

Is this a special treatment under the London Local Authorities Act?

- No, we do not consider this a special treatment under the London Local Authorities Act. However premises providing red-vein treatment using electrolysis will require a licence under the Act.

What does the treatment involve?

- Red vein treatment involves the injection of a substance into the vein. An injection of fluid is introduced which sticks the walls of the vein together so that blood cannot return. The vein walls that have been damaged by the injection are slowly removed by the body's natural defence mechanisms over a period of time.

What is the substance/product used?

- A number of products are available and manufactured by a number of companies. Each is considered to be a prescription only medicine (POM). These products are often referred to as sclerotherapy substances and are regulated by the Medicines Act.

Who may legally provide this treatment?

- The classification POM restricts the use of sclerotherapy substances only to a registered medical practitioner, or a person under the supervision and control of a registered medical practitioner. Beauty therapists should not legally provide the treatment without the prescription of and within a framework set and supervised by a medical practitioner.

Who is the health and safety enforcement authority?

- The decision for health and safety enforcement remains the same as that for botox. In most beauty establishments, enforcement will be the responsibility of the council.

Is this treatment regulated by the National Care Standards Commission?

- No, the Private Health and Voluntary Health Care (England) Regulations 2001 subcutaneous injection(s) of substances for cosmetic purposes from the definition of listed services under the Care Standards Act 2000.

## References and contacts

### Infection control and immunisations

#### The Health Protection Agency

Kirk House,  
97-109 High Street,  
Yiewsley,  
UB7 7HJ

☎ 01895 452087

@ londonnwHPU@hpa.org.uk

### Medical implants and their control

#### The Medicines and Healthcare Products Regulatory Agency

Hannibal House, London, SE1 6TQ

☎ 020 7972 8000

## Health and safety

### Health and Safety Executive

☎ HSE Info line: 08701 545 500

🌐 www.hse.gov.uk

### Hillingdon Council - Environmental Services

☎ 01895 250191

## Special treatment licenses

### Hillingdon Council - Environmental Services

@ envhealth-cp@hillington.gov.uk

☎ 01895 250191

## Registration with the National Care Standards Commission

### National Care Standards Commission

#### West London Area Office

58 Uxbridge Road,  
Ealing,  
London W5 2ST

## Doctors and registrations

### General Medical Council

178 Great Portland Street,  
London W1N 6AE

☎ 020 7915 3630

## Nurse practitioners, nurse prescribers and their regulations

### Nursing and Midwifery Council

23 Portland Place,  
London W1 B1P

☎ 020 7637 7181

## Review of this guidance note

This guidance note will be frequently reviewed in light of current knowledge and legal opinion. Any changes will be notified to licensees.

Up to date copies are available by phoning our office on ☎ 01895 250191.