# Safety In Medicine

## Student Training Guidelines

### Evaluation – Support – Feedback

* Evaluate your client’s experience to build confidence
* Collect feedback from client to build knowledge
* Learning to support yourself through head office

### Certification Requirements

* Question and answer time must be completed
* Answers must meet the pass criteria
* Theory work completed and marked prior to physical training

### Training Brief

* Rules and regulations
* Discrimination and equality
* Blown Aesthetics Code of conduct
* Training breakdown

### Practical assessments and evaluation

* Evaluation and question and answering
* Customer satisfaction

### What will we cover in theory training?

* Paper training manuals
* Paper documentation
* Skills and assessment ability
* Product evaluations and case studies

### What will students gain from theory learning?

* Product knowledge
* Science and factual evidence
* Industry knowledge
* Confidence
* Listening skills
* Professionalism
* How to approach a client
* How to deal with uneasy clients and the correct protocol
* Refund regulations on products
* Customer care
* Customer service
* Equality and discrimination
* Diversity
* Rules and regulations
* Codes of practise
* Laws and legislations

### Conducting practical training

* Interaction
* Hands on experience
* Evaluations
* Case studies
* Personal experiences
* Role play
* Health and safety
* Observational thinking
* Student input
* Allowing outspoken opinions.
* Showing the student how to complete customer disclaimers
* Demonstrations

### What student benefits will they gain from practical learning?

* Data protection knowledge
* Record keeping
* Filling out disclaimers and filing procedures
* Practical application
* Health and safety
* Professionalism
* Customer objections
* Observational hazards
* Cross contamination/infection

**Please note:** Students must be well presented and have their hair tied back. Students that arrive any later than ten minutes into a training session will not be able to enter the session. This is a distraction for others also attending training.

Blown Aesthetics would like to take time to thank you for training with us and we hope that you enjoy your experience.

## Some Objectives

* How to operate POM
* How to explain general sale medicines
* How to offer safe medicines
* How to explain the difference between medical and aesthetics

## Level 3 Diploma - Safe Practise In Medicines

### Introduction Aesthetic Medicines

Aesthetic Medicine is a developing clinical subspecialty and field in scientific research aimed at the use of minimally invasive cosmetic treatments to enhance patients' satisfaction with their physical appearance.

Training is a significant investment in your career in medical aesthetics. Courses can start at approximately £700 for just one day of training, but can go up to £10,000 depending on what exactly you wish to learn and to what grade.

There is likely no such thing as the best so, whether you are new to aesthetic medicine, or looking to improve your current technique, The most important question to ask you before investing in further education or training is, ‘where will this take me?’

Do you want a broad overview of injectables?

This Industry is a very competitive industry and a safety in medicines understanding is a must to be successful. Aesthetic medicine is a specialist area, its also undertaken by registered & licensed medical practitioners, comprising a range of surgical and non-surgical procedures or treatments, performed with topical or local anaesthesia, to restore, enhance, or modify the appearance, anatomy or physiology of the coetaneous, subcutaneous tissues or associated structures, using techniques which combine aesthetic considerations with the treatment or prevention of diseases , disorders or conditions in the promotion of the physical and mental health of patients.

We recommend that aesthetic practitioners become members of an association for aesthetic medicine. This medication online course provides all the knowledge requirements for the safe control, handling and administration of medicines in both social and domiciliary care environments and through non-medical careers such as aesthetical environments.

### HEE Guidelines

#### What is HEE?

Health Education England (HEE) is a Non-Departmental Public Body (NDPB), As of 1 April 2015, under the provisions of the Care Act 2014.

It is sponsored by the Department of Health. It leads education and training in the UK healthcare system.

Lack of regulation in the booming cosmetic industry is a significant cause for concern. Unsafe practice and substandard treatments are unacceptable for patient safety and public confidence in the specialty.

As a result of the Professor Keogh report, Health Education England was commissioned by the Department of Health to develop standards for training. During this consultation, experts from throughout the cosmetic sector contributed to new guidelines which set out to improve training and patient safety.

#### What are the key requirements?

Ofqual-regulated qualifications are required for a range of minimally invasive procedures, including:

* Chemical skin peels
* Microneedling
* Laser procedures
* Injectables (botulinum toxins and fillers)
* Hair restoration surgery

#### What are HEE trying to improve?

1. **Consent patients yourself.** It is essential to a shared understanding of expectations and limitations that consent to a cosmetic intervention is sought by the ACP who will perform it, or supervise its performance by another practitioner.
2. **Give patients an appropriate amount of time for reflection.** Make sure patients are given enough time and information before they decide whether to have an intervention. How do you calculate an appropriate amount of time? The GMC say the time will vary depending on the invasiveness, complexity, permanence and risks of the intervention. For injectable treatments, these will be at the lower end of the scale.
3. **Consider your patient’s psychological needs.** You must satisfy yourself that the patient’s request for the cosmetic intervention is voluntary.
4. **Work within your competency.** Before carrying out an intervention for the first time yourself, or supervising others performing it, you must make sure you can do so safely, eg by undergoing training or seeking opportunities for supervised practice. Seek advice or refer on when necessary.
5. **Inform patients of the risks.** Make sure patients have the information they want or need, including written information that supports continuity of care and includes relevant information about the medicines or devices used — and this should be done at the outset, not after the treatment. What else counts as a risk? The failure of an intervention to achieve the desired aim.
6. **Take care with children and young people.** Make sure younger patients want the procedure themselves, irrespective of whether their parent(s) consent to it.
7. **Market honestly and responsibly.** You should be able to attract patients without making unjustifiable claims about interventions, trivialising the risks involved, or using promotional tactics that might encourage people to make ill-considered decisions.

### The Medicines Act 1968

The legal requirements that apply to the sale, supply, dispensing and labelling of each class are dealt with separately below. Meaning of “retail sale” and “wholesale dealing” The selling of a medicinal product constitutes “wholesale dealing” if it is sold to a person for the purpose of: (a) selling or supplying it, or (b) administering it, or causing it to be administered to one or more human beings, the sale, supply or administration being in the course of a business carried on by the purchaser. Any sale that does not fall within this definition of “wholesale dealing” is a retail sale. The restrictions on the retail sale of medicinal products also apply to supply and to supplying “in circumstances corresponding to retail sale”, which includes the dispensing of prescriptions under the Health Service.

## There are 3 categories of medicine which are as follows:

### Prescription-only medicines (POM)

Which may be sold by a pharmacist if they are prescribed by a prescriber.

A PO medicine is a product that is licensed as a GSL medicine, but is restricted to sale through pharmacies only. PO medicines do not need to be sold under the supervision of a pharmacist. These medicines may be available for self-selection by members of the public.

Prescription Only Medicines are those medicinal products described as such in the Prescription Only Order. The main classes of Prescription Only Medicines are as follows:

* Medicinal products which a marketing authorisation has been granted and in the marketing authorisation are classified as being prescription only medicines;
* medicinal products which no marketing authorisation has been granted consisting of, or containing a specific substance
* Medicinal products that are for parental administration
* Medicinal products that are Controlled Drugs unless a marketing authorisation has been granted in respect of that medicinal product whereby the product is classified as being a Pharmacy or General Sale List Medicine;
* cyanogenetic substances, other than preparations for external use
* Medicinal products that on administration emit radiation or generate any substance that emits radiation, in order that radiation may be used
* Medicinal products in respect of which marketing authorisation has been granted consisting of, or containing, aloxiprin, aspirin, or paracetamol in the form of non-effervescent tablets or capsules that are classified as being pharmacy only or general sale list medicines.
* Medicinal products in respect of which a marketing authorisation has been granted consisting of or containing pseudoephedrine salts or ephedrine base or salts in all pharmaceutical forms which in the market

### Pharmacy medicines (P)

Which may be sold by a pharmacist without a prescription.

A Pharmacy medicine means a medicinal product that is not a Prescription Only Medicine and is either:

* Not a medicinal product on a General Sale List
* Products for human use containing aloxiprin, aspirin, paracetamol or salicylamide that are offered or exposed for sale by retail in packs which do not contain aspirin, or where the amount of aspirin in each tablet does not exceed 325 milligrams, more than 30 tablets
* Where the amount of aspirin in each tablet exceeds 325 milligrams, but does not exceed 500 milligrams in more than 20 tablets;
* In the case of tablets that are not effervescent, where they are enteric coated tablets, containing more than 75mg aspirin only, more than 28 tablets, or where they contain aloxiprin or paracetamol or a combination of any or all of these substances, more than 16 tablets;
* In the case of powder or granules, more than 10 sachets
* in the case of capsules, where they contain aloxiprin, aspirin or paracetamol or a combination of any or all of those substances, more than 16 capsules;
* in the case of liquid preparations of paracetamol, intended for persons aged 12 years and over, more than 160 ml, intended for persons less than 12 years, individual doses of more than 5 ml each, or more than 20 unit doses;
* Tablets for human use containing bisacodyl that are offered or exposed for sale by retail in containers or packages containing more than 40 tablets;
* Products for human use containing ibuprofen that are offered or exposed for sale by retail in containers or packages containing:
  + In the case of tablets, more than 16 tablets;
  + In the case of capsules, more than 16 capsules;
  + In the case of powders or granules, more than 12 sachets;
  + In the case of a product for topical use, more than 2.5g of ibuprofen
  + In the case of liquid preparations, unit doses of more than 5mls each, or more than 20 unit doses.
* Products for topical human use containing clotrimazole that are offered or exposed for sale by retail in containers or packages containing more than 500 milligrams of clotrimazole;
* Products for human use containing sodium picosulphate in a container or package of more than 60 ml of the product
* Products for human use containing loperamide hydrochloride in a container or package of more than 6 tablets or capsules;
* Omeprazole 10mg;
* Statins - simvastatin 10mg;
* Products for human use containing ranitidine hydrochloride in a container or package of more than 12 tablets;
* Products for human use containing famotidine in a container or package of more than 12 tablets;
* Products for human use containing heparinold in a container or package of more than 20g of the product;
* Products for human use containing ibuprofen lysine in a container or package containing more than 16 tablets

### General sales list (GSL)

Medicines, which may be sold without a prescription in any shop. Part of the GSL order specifies certain classes of medicinal products for human use that shall not be available on general sale.

They are medicinal products promoted, recommended or marketed:

* for use as anthelmintics,
* for parenteral administration,
* for use as eye drops,
* for use as eye ointments,
* for use as enemas,
* for use wholly or mainly for irrigation of wounds or of the bladder, vagina or rectum

All General Sale List medicines, except those that have been designated as foods or cosmetics, must be licensed products (it should be noted that a medicinal product, made up in a pharmacy for sale from that pharmacy without a marketing authorisation, is classified as a Pharmacy medicine even though all its ingredients are in the GSL Order).

Medicinal products that are for sale or supply either for oral administration as a food or for external use as a cosmetic are General Sale List medicines. This does not include products that are Prescription Only Medicines, eye drops or eye ointments, or any product that contains either: (a) vitamin A, vitamin A acetate or vitamin A palmitate with a maximum daily dose equivalent to more than 7,500 international units of vitamin A or 2,250 micrograms of retinol; (b) vitamin D with a maximum daily dose of more than 400 units of antirachitic activity.

## Botox

Botox is used medically to treat certain muscular conditions, and cosmetically to remove wrinkles by temporarily paralyzing muscles. It is made from a neurotoxin called **botulinum toxin** that is produced by the bacterium **Clostridium botulinum**.

Clostridium botulinum, the bacterium from which Botox is derived, is found in many natural settings, including soil, lakes, and forests. The bacterium can also be found in the intestinal tracts of mammals and fish and in the gills and organs of crabs and other shellfish.

Such naturally occurring instances of Clostridium botulinum bacteria and spores are generally harmless. Problems only arise when the spores transform into vegetative cells and the cell population increases. At a certain point, the bacteria begin producing botulinum toxin, the deadly neurotoxin responsible for botulism. Neurotoxins target the nervous system, disrupting the signalling processes that allow neurons to communicate effectively. Botulinum toxin is one of the most poisonous substances known to man. Scientists have estimated that a single gram could kill as many as 1 million people and a couple of kilograms could kill every human on earth. In high concentrations, botulinum toxin can result in botulism, a severe, life-threatening illness. Botulism, left untreated, may result in respiratory failure and death. Despite botulinum toxin being so toxic, Botox is in huge demand.

Despite this, botulinum toxin has proven to be a successful and valuable therapeutic protein. Botulinum toxin can be injected into humans in extremely small concentrations and works by preventing signals from the nerve cells reaching muscles, therefore paralyzing them.

Botulinum toxin is predominantly used as a treatment to reduce the appearance of facial wrinkles and fine lines.

Botulinum toxin is currently approved for the following therapeutic applications:

* Blepharospasm (spasm of the eyelids).
* Idiopathic rotational cervical dystonia (severe neck and shoulder muscle spasms).
* Chronic migraine.
* Severe primary axillary hyperhidrosis (excessive sweating).
* Strabismus (crossed eyes).
* Post-stroke upper limb spasticity.
* Detrusor (bladder wall muscle) overactivity - causing urinary incontinence.
* Overactive bladder.
* Hemifacial spasm.
* Glabellar lines (frown lines between the eyebrows).
* Canthal lines (crow's feet).

Injections with botulinum toxin are generally well tolerated and there are few side effects. In rare cases, an individual may have a genetic predisposition that results in a mild, transient unusual response to the drug.

Around 1 percent of people receiving injections of botulinum toxin type A develop antibodies to the toxin that make subsequent treatments ineffective.

Along with its intended effects, botulinum toxin may cause some unwanted effects. These can include:

* Mild pain, local edema (fluid buildup) and/or erythema (reddening of the skin) at the injection site.
* Numbness.
* Headache.
* Mild nausea.
* Temporary unwanted weakness/paralysis of nearby muscles.
* Temporary upper lid or brow ptosis (drooping).
* Weakness of the lower eyelid or lateral rectus (a muscle controlling eye movement).
* Dysphagia - trouble swallowing.
* Neck weakness.
* Flu-like illness.
* Brachial plexopathy - a condition affecting the nerves either side of the neck and chest.
* Gallbladder dysfunction.
* Diplopia (double vision).
* Bleeding.
* Blurred vision.
* Decreased eyesight.
* Dry mouth.
* Fatigue.
* Hives.
* Rashes.
* Wheezing.
* Swelling.

## Fillers

There are a variety of FDA and UK approved filler products that medics and non-medics use. In general, fillers are categorized by the substance they are made from. A note for your safety: always make sure that you are receiving FDA or UK approved, brand name fillers.

### Hyaluronic Acid (HA)

Hyaluronic acid is a naturally occurring substance that is already found in your skin. It helps keep skin plump and hydrated. HA fillers are typically soft and gel-like. The results are temporary, lasting 6 to 12 months or longer before the body gradually and naturally absorbs the particles. Most HA fillers are infused with lidocaine to help minimize discomfort during and after treatment. FDA and UK approved HA fillers include:

* Juvéderm products: Juvéderm XC, VOLUMA, VOLBELLA, VOLLURE
* Restylane products: Restylane, Restylane Silk, Restylane Lyft, Restylane Refyne, and Restylane Defyne
* Belotero Balance

### Calcium Hydroxylapatite (CaHA)

Calcium hydroxylapatite is also a naturally occurring substance, found primarily in our bones. When used in a filler, the calcium particles are nearly microscopic and suspended in a smooth gel. The consistency of a CaHA filler is typically thicker than that of a hyaluronic acid filler and typically last longer as well, about 12 months for most patients. Calcium hydroxylapatite is also reported to help stimulate natural collagen production, and it is typically used for deeper lines and wrinkles. FDA approved CaHA fillers include Radiesse®.

### Poly-L-lactic Acid

Poly-L-lactic acid is a biocompatible (meaning it is safe to use in the body), biodegradable synthetic substance. It has been used for many years in medical devices, such as dissolvable stitches. Poly-L-lactic acid products are technically classified as “collagen stimulators,” as their main mechanism to smooth fine lines is by helping your skin rebuild natural collagen—the filler gel itself dissipates a few days after treatment. Poly-L-lactic acid is typically used to treat deeper facial wrinkles, and results can last more than 2 years. FDA approved Poly-L-lactic acid fillers include Sculptra® Aesthetic.

### Polymethylmethacrylate (PMMA)

Polymethylmethacrylate (PMMA) is a synthetic, biocompatible substance that has been used in medicine for much of the last century. In dermal fillers, PMMA takes the form of a “microsphere” or tiny ball, that remains beneath the skin indefinitely to provide continued support. PMMA fillers will also contain collagen, a naturally occurring substance in the skin that provides structure and firmness. FDA approved PMMA fillers include Bellafill® (formerly known as Artefill).

### Autologous fat injections (facial fat grafting)

Autologous fat injections are the only injectable filler treatment that requires surgery, but results can last for many years. Your own fat is harvested from another area (autologous means “from the same person”), typically using liposuction. The fat is then purified and injected into the face to help restore volume to the cheeks, temples, lower eyelids, or other areas. Fat injections require specialized training to perform safely and achieve great results, and should only be performed by an experienced, board certified cosmetic surgeon.

## Questions

1. Explain ways in which complications can be avoided when delivering consultations in relation to medicines.
2. Explain the different types of medicine groups.
3. Explain the importance of knowing intra-condonations between medicines and other medicine groups.
4. Explain the importance of joining a medial association as a non-medical aesthetic practitioner.
5. Explain the importance of assessing mental health needs prior to any form of medical or aesthetic treatment being administered.

## Questions

1. Describe legislation and guidelines relating to the safe handling of medicines.
2. What year was the medicines act approved in?
3. Name the three types of medicine.
4. Name one policy and procedures that is legislated to ensure the safe handling of medicines.
5. Outline the process for the prescribing, dispensing, obtaining and checking of POM medicines.
6. Explain why it is important to ensure confidentiality relating to disclosure about individual’s medication.
7. Explain the routes by which medicines may be administered.
8. Give examples of the related rules for administration and explain the level of competence required.
9. Why is it important to check and recognise for reporting effects that can occur as a result of an adverse reaction, a contraindication or an interaction between medicines.
10. Explain the importance of recording medication errors.
11. Recognise the requirements to validate the accuracy of safe storage and recording for medicines and for their safe disposal.