

Licensing of non-surgical cosmetic procedures

Royal Pharmaceutical Society Response

Do you currently work in the cosmetic procedures sector as a practitioner who administers non-surgical cosmetic procedures?

- yes
- no

Do you have relevant qualifications specific to working in the non-surgical cosmetics sector?

- yes
- no

If you answered yes, please list your relevant qualifications.

Have you undergone any non-surgical cosmetic procedures in England?

- yes
- no
- prefer not to say

If you answered yes, what was the procedure or procedures?

Were you satisfied with the outcome of your procedures?

- yes
- no

Please explain your answer.

Were you satisfied with the expertise and approach of the practitioner who performed the procedures?

- yes
- no

Please explain your answer.

Do you feel you were adequately informed about what to expect and any potential risks before undergoing the procedures?

- yes
- no

Please explain your answer.

To better protect individuals who choose to undergo high-risk non-surgical cosmetic procedures, we propose introducing regulations to ensure that these procedures may only be undertaken by qualified and regulated healthcare professionals.

To what extent do you agree or disagree that we should set out in regulations that high-risk procedures should be restricted to qualified and regulated healthcare professionals only?

- **strongly agree**
- agree
- neither agree nor disagree
- disagree
- strongly disagree
- don't know

Please explain your answer

We agree that these high-risk procedures should only be undertaken by qualified and regulated healthcare professionals. However, we are aware that aesthetics is not normally covered in undergraduate training, so we would recommend that all healthcare professionals who undertake these high-risk procedures are suitably trained and qualified and they can demonstrate this.

To what extent do you agree or disagree with the proposal to amend CQC's regulations to bring the restricted high-risk procedures into CQC's scope of registration?

- **strongly agree**
- agree
- neither agree nor disagree
- disagree
- strongly disagree
- don't know

Please explain your answer.

This would bring these high-risk procedures in line with other procedures that are undertaken by regulated healthcare professionals. Pharmacist practice is regulated by the General Pharmaceutical Council, as are pharmacy premises. If certain practices are to be regulated by CQC then more clarity is needed as to how CQC would work with the GPhC in this area. We understand that GPhC would regulate the individual pharmacists and CQC would regulate the premises and practice, but there is likely to be some overlap, and this needs to be taken into consideration. In addition, would CQC be responsible for governing all cosmetic procedures by healthcare professionals and where would the distinction be between cosmetic and non-cosmetic procedures, for example the use of botox for excessive sweating?

These high-risk procedures should only be undertaken by trained and regulated healthcare professionals who have undergone specialist training in these areas.

The 3-tier system uses green, amber and red to categorise procedures depending on the risks (including level of complexity and degree of invasiveness) and potential complications associated with the procedure.

To what extent do you agree or disagree with using the 3-tier system to classify the different categories for cosmetic procedures based on the risk they to the public?

- strongly agree
- **agree**
- neither agree nor disagree
- disagree
- strongly disagree
- don't know

Please explain your answer.

It is useful to categorise the types of procedures in relation to risk to patient safety and harm. We agree with the proposal to cluster procedures into categories and that specific procedures are set out in accompanying guidance.

To what extent do you agree or disagree with the categorisation of the procedures listed in the green category?

- strongly agree
- agree
- neither agree nor disagree
- disagree
- strongly disagree
- don't know

Please explain your answer.

These appear to be lower risk procedures that do not require healthcare professional oversight. However, all practitioners undertaking these procedures should undertake relevant training and be named on the relevant register. The consultation document mentions that those undertaking these procedures will have to meet agreed standards and it would be useful to see what is included in these standards.

However, we believe that some of these procedures could be deemed as higher risk, dependent on the level at which they are applied. The categories within this section are too broad.

In addition, if pharmacists are undertaking these procedures within the registered pharmacy, their premises are already regulated by the GPhC. This means that they should not require further licensing by the local authority.

Do you think that any changes should be made to the listed procedures?

- procedures should be added
- procedures should be removed
- moved to another category (amber or red)

Please explain your answer.

- Microneedling is an invasive procedure and can lead to soft tissue damage if undertaken incorrectly so should not be included in this category. This should be moved to the amber or red category, depending on the meaning of 'clinical oversight' as explained in answers below.
- Mesotherapy traditionally would be classed in a low-risk category. However, the treatment has recently evolved to include the injection of a bolus of product into the sub-dermal layer of skin, and this would be seen as a higher risk procedure.
- No-Needle fillers have been banned by the FDA¹ and can be a high-risk procedure so should not be in this category
- The category of photo rejuvenation is too broad. Laser treatment can be carried out at different levels of the skin, mild to deep. The milder laser treatments could be included in this green category, but the deeper penetration of laser under the skin would need to be in a different category.

¹ <https://www.fda.gov/medical-devices/safety-communications/do-not-use-needle-free-devices-injection-dermal-fillers-fda-safety-communication>

To what extent do you agree or disagree with the categorisation of the procedures listed in the amber category?

- **strongly agree**
- **agree**
- **neither agree nor disagree**
- **disagree**
- **strongly disagree**
- **don't know**

Please explain your answer.

These procedures contain more risk than those on the green list in terms of patient safety and harm as they are more invasive. Clarity is needed in terms of what 'oversight by a named regulated healthcare professional' entails and how this would work in practice. Without this clarification it is difficult to respond as to what procedures should be included in this category. Would this healthcare professional be responsible for 'signing off' the aesthetic practitioner, for example?

There needs to be a transparent clarification of professional oversight. We recommend that this means that a regulated healthcare professional, who is a prescriber, always has clinical oversight on the premises so they can make the clinical assessments and clinical decisions and deal with any complications that arise. As the prescriber, they are responsible for the prescribing of the treatment, such as botox and fillers, and have ultimate responsibility for how that is used to treat a person. The prescriber is responsible for undertaking the clinical assessment and seeing the person before treatments are given, the aesthetic consultation is different to this. The aesthetic practitioner undertaking the treatment needs to have undertaken appropriate training to administer the treatments.

In addition, if pharmacists are undertaking these procedures within the registered pharmacy, their premises are already regulated by the GPhC. This means that they should not require further licensing by the local authority.

Do you think that any changes should be made to the listed procedures?

- **procedures should be added**
- **procedures should be removed**
- **moved to another category (green or red)**

Please explain your answer.

This is all dependent on what 'oversight by a named regulated healthcare professional' means in practice. If the prescribing healthcare professional is not on the premises providing clinical oversight then we would recommend that the following procedures are moved to the red category:

- Botulinum toxin and dermal fillers
- Vitamin and mineral injections
- Platelet rich plasma
- Weight loss injections

If a cosmetic procedure breaches the skin, then this should require clinical oversight where a prescriber is on the premises and has initiated Standard Operating Procedures for all of the treatments being given. It is not suitable that administration of a product is undertaken without a consultation with the prescriber responsible for prescribing the product.

The use of hyaluronidase, used for the dissolution of hyaluronic acid filler, could be added to either the amber or red category with the caveats outlined above in terms of clinical oversight. All those trained to administer fillers should also receive training on the dissolution of fillers.

Radiofrequency alone at low intensity does not need to be amber, and could be moved to the green category

To what extent do you agree or disagree with the categorisation of the procedures listed in the red category?

- strongly agree
- agree
- neither agree nor disagree
- disagree
- **strongly disagree**
- don't know

Please explain your answer.

These are high risk procedures and should only be undertaken by regulated healthcare professionals. There needs to be agreement between GPhC and CQC in terms of regulation and accreditation of the individual pharmacist as well as accreditation and regulation of premises.

Do you think that any changes should be made to the listed procedures?

- **procedures should be added**
- procedures should be removed
- moved to another category (green or amber)

Please explain your answer.

Again, this is all dependent on what is meant by 'clinical oversight by a regulated healthcare professional' and how this is undertaken in practice. If the regulated prescribing healthcare professional is not on the premises to provide clinical oversight, then we believe that the following procedures should be included in the red category:

- Botulinum toxin and dermal fillers
- Vitamin and mineral injections
- Platelet rich plasma
- Weight loss injections

Our intention is that licensed procedures should be restricted to those above the age of 18 unless approved by a doctor and carried out by a healthcare professional. To what extent do you think that these procedures should be age-restricted?

- **all of the procedures should be age-restricted**
- some of the procedures should be age-restricted
- none of the procedures should be age-restricted

Please explain your answer.

These procedures should not be available to those under 18 years of age due to patient safety issues and to support mental health and wellbeing.

Do you have any other comments on the issues raised in this consultation?

- **yes**
- no

If you answered yes, please explain your answer

For this to be successful, all aesthetic training providers need to be robustly accredited and properly assessed before their training is made available to practitioners. Standards need to be set for training providers, relating to the level of practitioners they aim to provide i.e., at green, amber or red level. Aesthetics training is not currently governed and there is no oversight of training providers. This means that anyone undertaking aesthetic procedures such as botox, dermal fillers and PDO threads would have the relevant training. This would ensure consistency in approach and reassure people who have these procedures.

Training needs to be put in place to support non-regulated aesthetic practitioners to progress through the different levels of service provision.

To undertake aesthetic procedures a level of experience is needed. There is a need to move away from 1 or 2 day training courses. The current Level 7 aesthetic training is seen as a benchmark as it includes the observation and supervision of procedures. It also allows students to see the complexity of a number of cases and how to deal with complications that may arise. They experience exposure over a period of time and see different elements of cases. The outcome is a post-graduate diploma level qualification.

Aesthetic practice is a speciality area. There needs to be a method for those already in practice, to demonstrate their experience through recognition of prior learning in order to gain the relevant accreditation. Clarity is needed on which pathways to take to ensure training is at the required standards. This will ensure integrity within this area of practice.

High level aesthetic training must be available for all those practitioners eligible to prescribe aesthetic medicines. At present for example, Allergan allow pharmacist prescribers to prescribe and administer their products but do not support their practice or allow pharmacists to access their training. This is obviously a patient safety risk.

The person prescribing and administering the treatment has a duty of care from the start to the finish of the treatment.

Those successfully completing accredited training courses should be registered as such: either through their professional regulator, or by joining an aesthetic practitioner register. Any person completing an accredited training course would be issued with a license to practice, to the relevant level.

Clinical oversight will be needed when any when prescription medicines are involved. Anyone at any level using a POM, will need to be overseen by a regulated healthcare professional who is a prescriber. Pharmacists don't require any CQC accreditation for prescribing and supply of meds but if clinical oversight is required, will this be under the scrutiny of the CQC and will CQC accreditation of the healthcare professional be required? GPhC states that pharmacist prescribers can only prescribe for regulated healthcare professionals (add in statement), however, legally other prescribers, such as doctors, nurses, dentists do not have this restrictive advice. Guidance is given by NMC, GDC, GMC. There should be consistency across all healthcare professionals in this regard. Pharmacist prescribers should be able to prescribe treatments for any aesthetic practitioner who can demonstrate they have successfully completed the accredited training, and for whom the prescriber has clinical oversight.

Regulated healthcare professionals do not cover aesthetic procedures as part of their undergraduate training, so would need to demonstrate competency in this area before undertaking such procedures.

We believe that the premises in which aesthetic procedures are provided should also be licensed and inspected to ensure they comply with relevant standards including infection control.

What specifically will CQC be dealing with in terms of the high-risk (red) treatments and who can undertake these treatments – do individuals as well as premises need to have CQC accreditation?

GPhC recognises aesthetics procedures within the scope of practice for pharmacists. However, the HCPC does not, and clarity is needed around this for other regulated healthcare professionals who are also non-medical prescribers.

Scotland is stricter in terms of what aesthetic practitioners can undertake. Anyone providing aesthetic treatments need to be registered with HIS and learning should be taken from this process. Issues with this. Nurses, dentists, pharmacists and doctors who are HIS registered can hold stock of aesthetic treatments.

There is also an issue in terms of aesthetic products, and we would recommend that devices used in cosmetic / aesthetic treatments are licensed and regulated. Cosmetic products are seen as different to medicines and the injection of these products fall outside of current regulations. We would recommend that MHRA reconsider the licensing of aesthetic treatments such as dermal fillers.