

Response ID ANON-W21S-ZJZS-X

Submitted to Regulation of non-surgical cosmetic procedures
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Questions about the grouping of procedures

1 Proposed Group 1 procedures

Group 1 Procedures - Microneedling:

Should only be undertaken in a HIS regulated setting (Group 2)

Group 1 Procedures - Chemical peels that only affect the outermost level of skin:

Should be undertaken in either a licensed premises or in a HIS regulated setting (Group 1)

Group 1 Procedures - IPL/LED therapy:

Should be undertaken in either a licensed premises or in a HIS regulated setting (Group 1)

Group 1 Procedures - Use of lasers for tattoo removal:

Don't know

Group 1 Procedures - Laser hair removal:

Don't know

2 Proposed Group 2 procedures

Group 2 procedures - Mesotherapy (injection of certain drugs, or other products into the middle layer of the skin):

Should only be undertaken in a HIS regulated setting (Group 2)

Group 2 procedures - Injections of toxins (e.g. Botox®) for cosmetic purposes:

Should only be undertaken in a HIS regulated setting (Group 2)

Group 2 procedures - Injections of drugs for cosmetic purposes:

Don't know

Group 2 procedures - Injections of semi permanent dermal fillers in small quantities (<2ml - e.g. to reduce wrinkles, or plump lips):

Should only be undertaken in a HIS regulated setting (Group 2)

Group 2 procedures - Any other injections of a product, even if it is not a drug or toxin, for lifestyle or cosmetic purposes. (not including tattooing which is already licenced):

Don't know

Group 2 procedures - Medium depth peels (that penetrate and destroy the outer layer of skin fully and penetrate into the next layer or upper dermis):

Should only be undertaken in a HIS regulated setting (Group 2)

Group 2 procedures - Photo rejuvenation:

Should only be undertaken in a HIS regulated setting (Group 2)

Group 2 procedures - Radiofrequency treatments:

Should only be undertaken in a HIS regulated setting (Group 2)

Group 2 procedures - HIFU (high frequency ultrasound):

Should only be undertaken in a HIS regulated setting (Group 2)

Group 2 procedures - Cryolipolysis (the use of cold to destroy pockets of fat under the skin):

Should only be undertaken in a HIS regulated setting (Group 2)

3 Proposed Group 3 Procedures

Group 3 procedures - Platelet rich plasma, biotherapy or injections of any products derived from the patient's blood:

Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - Injection microsclerotherapy (use of injections to treat visible spider veins):

Should only be undertaken in a HIS regulated setting (Group 2)

Group 3 procedures - Injection lipolysis or injections of fat dissolving agents:

Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - Dermal micro coring (removal of small amounts of skin to reduce visible signs of aging):

Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - Hay fever injections:
Don't know

Group 3 procedures - Any procedure involving intravenous fluids or drawing and processing bloods for cosmetic or lifestyle purposes, for instance provision of intra venous vitamins and minerals, or intra venous blood oxygenation.:
Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - Use of dermal fillers for the purpose of augmentation of e.g. the breasts and buttocks:
Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - Deeper chemical peels such as phenol peels:
Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - All laser treatments not specified above, including lasers which target the deeper layers of the dermis.:
Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - Carboxytherapy (the injection of CO2 under the skin to promote collagen production):
Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - Cellulite subcision (making small incisions to reduce appearance of cellulite):
Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - Electrocautery (removal of skin tags through electricity):
Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - Cryotherapy and cryocautery (use of extreme cold to remove e.g. skin tags):
Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - Thread lifting and cogs (placement of dissolvable material under skin to tighten appearance and promote collagen):
Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

Group 3 procedures - All group 1 or 2 procedures where procedures are carried out in an intimate area (except hair removal and not including procedures such as tattooing and skin piercing which are already licenced):
Should be undertaken in a HIS regulated setting by an appropriate healthcare professional (Group 3)

4 Please provide any comments you have in relation to the grouping of procedures and the level of regulation required:

Please give us your views:

The Royal Pharmaceutical Society (RPS) agrees with the proposed approach to categorise the types of non-surgical cosmetic procedures in relation to risk of patient safety and harm. We agree with the proposal to cluster procedures into categories and that specific procedures are set out in accompanying guidance.

We also support the aims to ensure that people accessing these procedures can do so from appropriately trained practitioners, in a clean and safe environment that meets the necessary standards to promote client safety. We agree with the detail described in the proposals about the level of supervision required of practitioners by healthcare professionals for Group 2 procedures.

Ensuring that the individual practitioners, premises, medicines and medical devices (through MHRA) involved in these procedures are regulated, alongside the classification of the procedures into categories, allows a proportionate arrangement which supports the industry, supports client choice and ensures the highest standards from practitioners and healthcare professionals practicing in this field.

The RPS has published a view on Pharmacy and Aesthetic Practice (2019) where we state:

Pharmacists who wish to expand their scope of practice should have access to, and undertake, the appropriate training. The Joint Council for Cosmetic Practitioners (JCCP) holds a register of approved training providers and a list of registered practitioners. In order to register with JCCP, practitioners must demonstrate the necessary level of competence for the procedures they wish to carry out.

Non-surgical aesthetic procedures such as Botox and dermal fillers are usually private treatments, requiring a physical examination. Similarly to any area of practice, whether prescribing or delivering these services, pharmacists must make sure they have the correct knowledge, skills and competence to keep patients safe.

RPS supports the code of practice from the JCCP and their competency framework which defines both the procedures pharmacists could undertake and the training required to do so.

We have specific comment about some of the procedures listed within the proposals:

Liposuction, hay fever injections, weight loss injections and topical prescription only medicines appear in the proposed Group 3 list but do not appear in the consultation questions.

Liposuction – due to the associated injection of local anaesthetic and the bore of the tube inserted we believe this should be in Group 3.

Hay fever and weight loss injections – these are not described in any detail in the consultation paper and therefore too vague to make an assessment.

Hay fever and weight loss injections must not be included in any of the groupings. Furthermore, hay fever injections should not be considered cosmetic procedures and reference to these should be removed from this process.

With reference to weight loss injections, these are not licensed to be used for cosmetic / aesthetic purposes and should only be used in the context of medically indicated weight loss under the supervision of a suitably qualified healthcare professional. This consultation process is an important opportunity to highlight that there are known and suspected issues with the supply of both licensed and counterfeit weight loss injections. There are legal and professional restrictions on the prescribing, supply and administration of these medicines and this is an opportunity to raise awareness of this to those working in the cosmetic and aesthetic industries.

Furthermore, the pharmacy regulator, the General Pharmaceutical Council (GPhC), has acknowledged the increased demand for, and associated risk surrounding, weight loss injections in its recent "Guidance for registered pharmacies providing pharmacy services at a distance, including on the internet"

describing the additional safeguards required. Weight loss injections must not be available through the non-surgical cosmetic procedures route. Microneedling is an invasive procedure and can lead to soft tissue damage if undertaken incorrectly so should not be included in this category. Consider moving to Group 2.

Chemical peels – we agree in principle with the higher group category dependent on the depth of the peel. However, it is unclear how the depth of the peel is controlled and how the differentiation between Groups 1-3 would be made when determining the procedure type and classification due to the variation in skin types.

Similarly for laser treatment, with varying depth of penetration, we agree with the principle that the deeper the treatment the higher the grouping. However, how will this be monitored and controlled?

“Injections of drugs for cosmetic purposes” is too vague and there must be clarity about the specifics within Group 2. Our preference is to use the term medicines in this context and a reference to the classification is important, e.g. GSL, P or POM. The type of injection must also be clarified. The licensed indication must also be taken into account. This comment is also relevant for the term “Any other injections of a product, even if it is not a drug or toxin, for lifestyle or cosmetic purposes.”

We agree that the medicine, formulation and method of administration, especially those given by injection must be taken into account and all prescription only medicines must be prescribed by the supervising health care professional. In addition, for Group 3 procedures where medicines are prescribed and administered intravenously these must be carried out by an appropriately trained, qualified healthcare professional within their scope of practice and we would expect the professional regulators to have insights into this field of practice when the professional is undertaking revalidation. We identified that there may be clients who wish to access more than one cosmetic procedure within one treatment, and we ask Scottish Government to consider how this might be best classified within the proposals.

Consideration must also be given to the availability of equipment, medicines and appropriately trained practitioners for the management of any medical emergency which occurs during a non-surgical cosmetic procedure.

For Questions 13 & 14 giving consideration to the registered healthcare professionals which can undertake Group 3 procedures. It is our position that these procedures must only be undertaken by a registered healthcare professional with independent prescribing qualifications. Therefore, we chose the best fit answer to Q13, and our understanding is that “suitably trained and qualified healthcare professional working within their scope of practice” would include prescribing rights and therefore, at this time, prevents dental care professionals and registered pharmacy technicians from undertaking group 3 procedures.

Furthermore, 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 Healthcare Improvement Scotland.

Questions about the proposed licensing regime

5 Do you support or oppose the proposal that the practitioner of a Group 1 procedure operating in a licensed premises should also require a licence?

Strongly support

6 Do you support or oppose the proposal that the practitioner of a Group 1 procedure operating in a HIS regulated setting should not require a licence?

Strongly oppose

7 Please provide any comments about the answers you have given to questions 5 and 6 about the proposals for the establishment of licensing arrangements for Group 1 procedures:

Please give us your views:

Any practitioner conducting Group 1 procedures must be appropriately trained and licensed. This is a safeguarding and assurance mechanism for the general public accessing these services. This should not be dependent on the premises in which the procedures are being conducted and should apply in all settings.

8 To what extent do you agree or disagree that the Scottish Government should establish:

Standards for Licenced premises - Standards of hygiene and health and safety for licensed premises?:

Strongly Agree

Standards for Licenced premises - Standards of training and qualification for licensed practitioners?:

Strongly Agree

Standards for Licenced premises - Mandatory insurance and indemnity to compensate clients who suffer harm as a result of negligence or malpractice?:

Strongly Agree

9 To what extent do you agree or disagree that local authority officers should have powers of inspection and enforcement, including:

Enforcement & Inspection powers for Local Authorities - The removing of a licence from premises or practitioners who cannot demonstrate compliance with standards established by the Scottish Government?:

Strongly Agree

Enforcement & Inspection powers for Local Authorities - Barring individuals from holding a licence if they are associated with serious or repeated non-compliance with the standards established by the Scottish Government?:

Strongly Agree

10 Which of the following statements do you agree with in relation to whether a vehicle can receive a licence as a premises? (Pick one)

I don't know

Questions about the restriction of procedures to a HIS regulated setting

11 To what extent do you agree or disagree that the Scottish Government should establish:

Standards of training and insurance for non-healthcare professionals - Standards of training and qualification for non-healthcare and healthcare professionals undertaking procedures in HIS regulated services?:

Strongly Agree

Standards of training and insurance for non-healthcare professionals - Mandatory insurance and indemnity to compensate clients who suffer harm as a result of negligence or malpractice?:

Strongly Agree

12 Do you agree or disagree that the healthcare professional supervising a group 2 procedure should:

Supervising healthcare professional - Conduct the / any initial consultation(s) with the client?:

Agree

Supervising healthcare professional - Prescribe any medications (e.g. Botox TM, lidocaine) required during the procedure, or required for the management of any complications that arise?:

Agree

Supervising healthcare professional - Remain available on site for the duration of any procedure?:

Agree

Supervising healthcare professional - Be responsible for ensuring the practitioner is suitably trained for the procedure?:

Agree

Supervising healthcare professional - Be responsible for ensuring the procedure will be undertaken safely?:

Agree

Supervising healthcare professional - Be themselves suitably trained and qualified in the procedure being undertaken?:

I don't know

13 Thinking about the healthcare professional undertaking a group 3 procedure, which statement below do you agree with:

These procedures should be undertaken by a suitably trained and qualified healthcare professional working within their scope of practice, but not otherwise be limited.

14 If your answer to the last question was that these procedures should only be undertaken by certain healthcare professionals, please tick all the healthcare professionals to which they should apply:

15 Do you agree or disagree that the following settings should be required to register with Healthcare Improvement Scotland if they are offering non-surgical cosmetic procedures?

Healthcare settings - HIS registration - GP practices:

I don't know

Healthcare settings - HIS registration - Dental practices:

I don't know

Healthcare settings - HIS registration - Community pharmacies:

Disagree

16 Do you agree or disagree that Healthcare Improvement Scotland should have powers of inspection, including powers of entry and inspection of unregistered settings where there is reason to believe registration is required?

Agree

Questions about age restrictions

17 Which of the following statements is closest to your view? (please select only one option)

There should be a lower age limit under which clients should not be allowed to undertake an NSCPs (different ages are considered in Question 18)

18 Regardless of your answer to question 17, if an age limit is to be put in place please indicate for each procedure group what you think is the appropriate age to be set for the procedures in that group.

Preferred Age Limit - Procedure Group 1:
Limited to clients aged 18 and over

Preferred Age Limit - Procedure Group 2:
Limited to clients aged 18 and over

Preferred Age Limit - Procedure Group 3:
Limited to clients aged 18 and over

19 Do you agree or disagree that procedures on intimate areas should only be available to clients of 18 years of age and over?

Agree

Questions about equalities, Fairer Scotland duty, impact on island communities and UNCRC

20 What are your views on how, if at all, the introduction of licensing and regulation of the non-surgical cosmetics sector in Scotland might affect anyone based on their protected characteristics?

Please give us your views.:

Ensuring that practitioners are licensed and regulated can improve the overall safety and quality of procedures, benefiting all individuals, especially those with disabilities or gender re-assignment. The licensing process must be inclusive to ensure that people and practitioners from minority backgrounds are not inadvertently disadvantaged. Young people may feel discriminated against as we believe the minimum age for these procedures is 18.

21 What are your views on how the introduction of licensing and regulation of the non-surgical cosmetics sector in Scotland might affect people differently based on their financial situation?

Please give us your views.:

Increased regulation might lead to higher costs for procedures, which could disproportionately affect individuals from lower socioeconomic backgrounds, potentially limiting access for some groups.

22 What are your views on how the introduction of licensing and regulation of the non-surgical cosmetics sector in Scotland might affect access to safe, high-quality services in island communities?

Please give us your views.:

There may be a higher cost for regulation and may reduce the availability of licensed practitioners in island communities, however, those services that do exist will benefit from higher standards of practice.

23 What are your views on how the introduction of licensing and regulation of the non-surgical cosmetics sector in Scotland and the potential of age restrictions might affect respecting, protecting and fulfilling the rights of children and young people as set out in the UN Convention on the Rights of the Child?

Please give us your views.:

Implementing age restrictions can protect children from undergoing procedures that they may not fully understand or that could have long-term health implications which links with Article 3: The best interests of the child must be a primary consideration in all actions concerning children.

About you

24 What is your name?

Name:
Fiona McIntyre

25 Are you responding as an individual or an organisation?

Organisation

26 What is your organisation?

Organisation:
Royal Pharmaceutical Society Scotland

27 Further information about your organisation's response

Please add any additional context:

28 Further information about your connection to the non-surgical cosmetic procedures sector

I am not involved in the non-surgical cosmetics sector

29 The Scottish Government would like your permission to publish your consultation response. Please indicate your publishing preference:

Publish response with name

30 Do you consent to Scottish Government contacting you again in relation to this consultation exercise?

Yes

31 What is your email address?

Email:

Fiona.McIntyre@rpharms.com

32 I confirm that I have read the privacy policy and consent to the data I provide being used as set out in the policy.

I consent

Evaluation

33 Please help us improve our consultations by answering the questions below. (Responses to the evaluation will not be published.)

Matrix 1 - How satisfied were you with this consultation?:

Slightly satisfied

Please enter comments here.:

Additional comments boxes after the multi choice questions would have been helpful to aid in justifying or explaining an answer more thoroughly.

Matrix 1 - How would you rate your satisfaction with using this platform (Citizen Space) to respond to this consultation?:

Very satisfied

Please enter comments here.: