

Response to DHSC consultation on licensing of non-surgical cosmetics in England

October 2023

1. Introduction

1.1 The Professional Standards Authority for Health and Social Care (PSA) promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at www.professionalstandards.org.uk

1.2 As part of our work we:

- Oversee the ten health and care professional regulators and report annually to Parliament on their performance
- Accredit registers of healthcare practitioners working in occupations not regulated by law through the Accredited Registers programme
- Conduct research and advise the four UK governments on improvements in regulation
- Promote right-touch regulation and publish papers on regulatory policy and practice.

2. General comments

2.1 We welcome the opportunity to comment on the Department of Health and Social Care (DHSC's) proposals for a licensing scheme for non-surgical cosmetics procedures.

2.2 We support the introduction of a licensing scheme to ensure that those who choose to undergo a non-surgical cosmetic procedure can be confident that the treatment they receive is safe and of a high standard.

2.3 Ahead of the introduction of a licensing scheme we are encouraging those seeking non-surgical cosmetic procedures to choose a practitioner on a register accredited under our [Accredited Registers programme](#).¹

2.4 We are also encouraging all eligible non-surgical cosmetic practitioners to join an Accredited Register to demonstrate their competence and reduce risk to the public.

2.5 On the areas within the consultation:

¹ The PSA has accredited two registers for non-surgical cosmetic practitioners [Save Face](#) and the [Joint Council for Cosmetic Practice \(JCCP\)](#). Accreditation provides assurance to the public and employers that practitioners are subject to high standards of competence and are covered by robust complaints processes, helping to ensure that people receiving care are better protected.

- We think it is important that the licensing scheme is simple and transparent to allow the public to easily understand requirements when choosing who to receive non-surgical cosmetic treatments from
- If the tiered system (red, amber, green) for non-surgical procedures of different levels of risk is implemented, then clear communications will be needed on what members of the public need to look for when seeking to access different kinds of treatments safely
- We support proposals in the consultation to set a minimum age of 18 for access to non-surgical cosmetic procedures
- We support proposals to remove high-risk procedures from the scope of the licensing scheme and bring them under additional regulatory oversight
- We think that there should be clear criteria for classifying non-surgical procedures as high, medium and low risk (red, amber, green) to allow this approach to be future-proofed and flexible to incorporate new and evolving procedures
- We think that, if possible, the scheme should recognise and complement existing regulatory mechanisms such as the Accredited Registers programme which is already acting to raise standards in the area of non-surgical cosmetics
- It will be important to ensure alignment of approach across the UK as far as possible, noting that action in this area is a devolved matter.

3. Answers to questions

Question 7 - 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?

3.1 Agree

Please explain your answer.

3.2 We support in principle proposals to remove particularly high-risk procedures from the scope of the licensing scheme (those in the 'red' category in the consultation) and apply a higher level of regulatory oversight.

3.3 The consultation proposes that these should only be carried out by 'qualified and regulated healthcare professionals.' It would be helpful to clarify whether all statutorily regulated healthcare professionals will be eligible to carry out such procedures or whether this will be limited to those where such procedures are more obviously within their scope of practice, or to those with specific skills or on a specific register.

- 3.4 It would also be helpful to understand how these requirements will be enforced, i.e. will professional regulators be expected to ensure that their registrants are only carrying out such procedures if they have the appropriate qualifications, and how will this work in practice. It also currently isn't clear from the proposals within the consultation document how unregulated, unqualified professionals will be prevented from carrying out these procedures.
- 3.5 We think further clarity is needed on how such requirements will be communicated to the public – how will the public know that the procedure they wish to undergo should only be carried out by a qualified and regulated professional as opposed to procedures that fall within other categories of the tiered system?
- 3.6 We think it would be helpful for there to be clear criteria on what should be included within the 'red' category and therefore falls outside of the licensing scheme. This will allow consideration of whether further treatments should be brought across from the other categories or whether future treatments which enter the market should be similarly restricted. It would also be helpful for there to be clarity on the process for updating the risk rating and the procedures that will fall into each category.
- 3.7 We note that the consultation currently lays out the following description of the types of procedure that the Government intends to restrict:
- *'procedures aimed at augmenting the genitals, typically using autologous fat or dermal fillers*
 - *any injectable procedures - such as dermal fillers - undertaken to intimate areas of the body, such as the rectum, genitalia or breasts*
 - *the combination of ultrasound and large bore cannula for the purposes of liposuction.'*
- 3.8 Whilst we think this provides a helpful overview of the kinds of procedures that are considered to be high-risk, it would be useful for it to be clear how these descriptors relate to the inherent risk of the different procedures and how this links to how medium and lower risk procedures have been categorised.
- 3.9 These descriptors may also need to be reviewed depending on whether other procedures are brought into scope of the higher restrictions either following the consultation or in the future.

Question 8 - 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?

- 3.10 Agree

Please explain your answer.

- 3.11 Whilst we can see the logic in bringing the procedures under Care Quality Commission (CQC) regulation as 'regulated activities', it would be helpful to understand how this will work in practice alongside the connected proposal to

restrict such procedures to be carried out only by 'qualified, regulated healthcare professionals.'

- 3.12 CQC's regulated activities legislation largely relate to services rather than individuals, for example the existing regulated activity legislation which covers surgical procedures (including cosmetic surgery) applies to services providing relevant procedures carried out by a healthcare professional but does not list which professionals are in scope.²
- 3.13 Clarity on how the proposals in the consultation will fit with the existing CQC approach and existing professional regulatory requirements in place through the healthcare professional regulators will be important. This links to the point we have raised in our previous answer about who will be expected to enforce requirements that only qualified and regulated healthcare professionals carry out red category procedures.

Question 9 - 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 present to the public?

- 3.14 Neither agree nor disagree

Please explain your answer.

- 3.15 We can see benefits in introducing a tiered system within the licensing scheme to account for the fact that certain procedures are higher risk than others and may require greater regulatory oversight.
- 3.16 However, we suggest that the DHSC carefully considers whether this approach is likely to be sufficiently clear to members of the public who will need to understand it in order to make informed choices about who they choose to treat them. Currently it appears that the burden of navigating the tiered system will fall to members of the public searching for a clinic or practitioner to undergo a non-surgical cosmetic procedure. Patients will need to know whether the procedure falls into the green, amber or red category in order to find out whether they are receiving treatment from someone who is competent and working within the law.
- 3.17 If the tiered system is implemented, then clear communications will be needed to help members of the public understand what to look for when seeking treatments within each different category to avoid confusion. We also think that further clarity is needed on the communications expectations on professionals, practitioners and providers of treatments, to support members of the public in accessing the services they need safely.

² The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 – Schedule 1, 'Surgical procedures': <https://www.legislation.gov.uk/ukxi/2014/2936/schedule/1>

- 3.18 As with our comments on the 'red' category of procedures which will fall outside of the licensing scheme, we think that DHSC should define criteria for placing a procedure in the 'green' (low risk) or 'amber' (medium risk) category. This will be important to ensure consistency of approach in how procedures are categorised and will also help with future proofing so that new and developing procedures can be classified appropriately in the future.

Question 10 - To what extent do you agree or disagree with the categorisation of the procedures listed in the green category?

- 3.19 Neither agree nor disagree

Please explain your answer.

- 3.20 We do not have the expertise to comment on whether the procedures listed in the green category are the correct ones. However, we would like assurance that there is an underlying logic in how procedures have been categorised based on risk.

- 3.21 As with our comments on the 'red' category of procedures which will fall outside of the licensing scheme, we think that DHSC should define criteria for placing a procedure in the 'green' (low risk) or 'amber' (medium risk) category. This will be important to ensure consistency of approach in how procedures are classified and will also help with future proofing so that new and developing procedures can be classified appropriately in the future.

Question 11 - Do you think that any changes should be made to the listed procedures?

- 3.22 No comments.

Please explain your answer.

- 3.23 No comments.

Question 12 - To what extent do you agree or disagree with the categorisation of the procedures listed in the amber category?

- 3.24 Neither agree nor disagree

Please explain your answer.

- 3.25 We do not have the expertise to comment on whether the procedures listed in the amber category are the correct ones. However, we would like assurance that there is an underlying logic in how procedures have been categorised based on risk and would echo our comments made in relation to the red and green categories that there should be clear criteria on the basis for placing procedures within the different categories.

- 3.26 We think that further clarification is needed in relation to proposals for the amber category (medium risk) to understand how these proposals will operate in practice.

- 3.27 The consultation document specifies a range of procedures which can only be carried out by a licensed practitioner: 'with relevant oversight by a named,

regulated healthcare professional (who has gained an accredited qualification to prescribe, administer and supervise aesthetic procedures)'.³

3.28 Our queries on this include:

- What is meant by regulated healthcare professional and how will the holding of an accredited qualification be enforced?
 - Will all statutorily regulated professionals be in scope, or will this be limited to those whose scope of practice more obviously covers the carrying out of non-surgical cosmetic procedures, or to those with specific skills or on a specific register? For example, the Botulinum Toxin and Cosmetic Fillers (Children) Act 2021 lists registered nurses, dentists and pharmacists alongside medical professionals as the regulated professionals who might have legitimate reason to administer specified substances.³
 - Who will enforce the requirement for statutorily regulated professionals providing oversight of non-surgical cosmetic procedures to hold an accredited qualification?
- What is meant by 'relevant oversight' and are there any unintended consequences arising from the model proposed?
 - Will clinics providing such treatments be required to have an appropriate regulated professional on site at all times?
 - What level of involvement will the supervising regulated healthcare professional have in client consultations and treatments, including where prescribed substances are involved?
 - Is there a risk of unintended consequences in exacerbating workforce pressures if regulated healthcare professionals move out of the NHS and into oversight roles for providers of non-surgical cosmetic procedures?
- How do current rules and approaches taken by the statutory professional regulators around prescribing fit with this model?
 - As it stands, some regulators and professional bodies prevent or discourage registrants from using their prescribing rights for activities/employment outside their primary scope of practice. For example, the Health and Care Professions Council (HCPC) have clarified that prescribing rights are tied to professional registration, job description and indemnity cover, therefore anyone qualified as a non-medical prescriber in one role e.g. a paramedic, but working in a different role should not be prescribing.⁴

³ Botulinum Toxin and Cosmetic Fillers (Children) Act 2021:
<https://www.legislation.gov.uk/ukpga/2021/19/section/1/enacted>

⁴ A joint statement of support from the Health and Care Professions Council and the College of Paramedics, 2020. Available at: <https://www.hcpc-uk.org/registrants/updates/2020/a-joint-statement-of-support-for-paramedics/>

- There are also different approaches around remote prescribing across the professional regulators.

Question 13 - Do you think that any changes should be made to the listed procedures?

3.29 No comments.

Please explain your answer.

3.30 No comments.

Question 14 - To what extent do you agree or disagree with the categorisation of the procedures listed in the red category?

3.31 Neither agree nor disagree

Please explain your answer.

3.32 We do not have the expertise to comment on whether the procedures listed in the red category are the correct ones – other respondents may be better placed to do so. However, as we have highlighted in our response to other questions, we think it is important that there is an underlying logic in how procedures have been categorised based on risk and clear criteria for placing procedures in the different categories.

3.33 Although DHSC have already suggested criteria for how the existing list of red procedures have been selected it will be important to be clear on how these are linked to the inherent risk of the procedures (and the categorisation of other procedures). This will help to ensure consistency of approach in how procedures are classified and help with future proofing so that new and developing procedures can be classified appropriately in the future.

Question 15 - Do you think that any changes should be made to the listed procedures?

3.34 No comments.

Please explain your answer.

3.35 No comments.

Question 16 - 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?

3.36 All of the procedures should be age-restricted.

Please explain your answer.

3.37 We fully support introducing a minimum age of 18 for accessing the non-surgical cosmetic procedures within the scope of the licensing scheme.

- 3.38 This is in line with the restrictions previously introduced by the Government on providing botulinum toxin and cosmetic fillers in 2021⁵ and it is an important way of ensuring that those seeking non-surgical cosmetic procedures are old enough to make informed decisions about potentially significant procedures.
- 3.39 We note the risk of unintended consequence arising when there is variation on who can access such procedures across the UK with recent reports that under 18s in England are now travelling to Wales to access Botox and lip fillers.⁶ We urge DHSC to work closely with colleagues in the devolved nations to maintain four-country consistency as far as possible.

Question 17 - Do you have any other comments on the issues raised in this consultation?

- 3.40 Yes

If you answered yes, please explain your answer.

Coverage of licence

- 3.41 It would be helpful to have further clarity on who will be required to apply for/hold a licence under the scheme. The suggestion is that qualified and regulated professionals will be exempt from requirements to hold a licence, however this isn't stated explicitly.

Interaction with existing regulatory mechanisms, including the Accredited Registers programme

- 3.42 We note the approach consulted upon by the Welsh Government within their consultation on licensing of special procedures in Wales of proposing exemptions for statutorily regulated healthcare professionals but not qualified practitioners on a PSA Accredited Register. We queried this approach on the grounds that it could disincentivise membership of an Accredited Register by creating an additional layer of regulatory burden on those who are already a member of an AR.⁷
- 3.43 We would like to emphasise the value of the Accredited Registers programme in raising standards within non-surgical cosmetics and we think this should be taken into account when considering how the licensing scheme interacts with such requirements which are already in place.
- 3.44 If it is DHSC's intention to only require those that are not statutorily regulated to apply for a licence to carry out procedures either alone (green category) or

⁵ Botulinum Toxin and Cosmetic Fillers (Children) Act 2021:

<https://www.legislation.gov.uk/ukpga/2021/19/section/1/enacted>

⁶⁶ BBC, 18 October 2023, *Botox: Under-18s come to Wales after England bans practice*. Available at: <https://www.bbc.co.uk/news/uk-wales-67122138>

⁷ Professional Standards Authority 2023, *Response to Welsh Government consultation on Mandatory Licensing of Special Procedures in Wales*. Available at:

https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2023/psa-response-on-wales-licensing-consultation.pdf?sfvrsn=60884a20_3

supervised (amber category) we think there should be consideration of the potential unintended consequences of this approach.

- 3.45 Similarly, it would be helpful to understand how the requirement for a premises licence will fit with existing regulatory requirements for providers. A number of clinics offering non-surgical cosmetic procedures are already likely to be CQC registered if they also offer other types of procedures.
- 3.46 It would be useful to confirm that the licensing scheme doesn't intend to duplicate other regulatory safeguards that are already in place for certain non-surgical cosmetic procedures – for example tooth whitening which is regulated by the General Dental Council (GDC).⁸

Consistency of approach across the UK

- 3.47 We think it is important to ensure alignment of approach across the UK as far as possible, noting that action in this area is a devolved matter. As it stands, the DHSC are not proposing to include within the licensing scheme for England the special procedures that the Welsh Government has recently consulted on requiring a licence for, including acupuncture.⁹ We are aware however that some of the procedures listed in the consultation on the scheme in England are sometimes seen as being within the scope of acupuncture.
- 3.48 As members of the public may access services in any part of the UK and registrants may practise across the UK, we would urge further consideration of whether greater consistency of approach is possible. We note the risk of potential unintended consequences arising from variation in approach across the UK, with recent reports in the media of under 18s in England travelling to Wales to access Botox and lip fillers following the introduction of restrictions on access in England.¹⁰ We welcome the references within the consultation to working closely with colleagues in the devolved administrations on further development of the English scheme.

Interaction with other regulatory developments

- 3.49 It would be helpful to understand how licensing proposals might link with other regulatory developments to address the range of risks present in the non-surgical cosmetics sector. This includes the recent consultation by the Medicines and Healthcare products Regulatory Agency (MHRA) which looked at extending medical device regulations to products commonly associated with cosmetic procedures such as microneedling products and dermal fillers.¹¹ It will be important that proposals for the licensing scheme complement other

⁸ General Dental Council, Tooth whitening and illegal practice: <https://www.gdc-uk.org/standards-guidance/information-for-patients-public/tooth-whitening-and-illegal-practice>

⁹ *Mandatory licensing of special procedures in Wales*. Available at: <https://www.gov.wales/mandatory-licensing-special-procedures-wales>

¹⁰ BBC, 18 October 2023, *Botox: Under-18s come to Wales after England bans practice*. Available at: <https://www.bbc.co.uk/news/uk-wales-67122138>

¹¹ Medicines and Healthcare Regulatory Authority, *Consultation on the future regulation of medical devices in the United Kingdom*. Available at: <https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom/outcome/chapter-1-scope-of-the-regulations#section-2---products-without-an-intended-medical-purpose>

regulatory changes and that interventions are appropriately targeted at the different types of risks present within the sector.

Clarity for patients and the public

- 3.50 As well as the clarity of the tiered system proposed, further consideration may be needed on how the scheme can be made accessible and navigable for members of the public searching for a licensed practitioner. For example, would a national register of licensed practitioners be required?
- 3.51 This links to the point we have raised earlier in our response about the balance of responsibilities on the public to understand what they should be looking for to keep themselves safe, and practitioners/providers themselves to communicate the requirements of the new system and ensure it is clear and accessible to potential customers.

Enforcement

- 3.52 It would be helpful to understand whether any consideration has been given to the resource required for effective enforcement of the licensing scheme. This will be particularly important if the scheme isn't straightforward for members of the public to navigate themselves.
- 3.53 We note that many local authorities may struggle to ringfence funds to implement an effective enforcement regime – the low rate of implementation of licensing schemes under existing legislation suggests that this may be a consideration. Although the scheme itself may be partially or fully self-funding it would be helpful to have clarity on this point to ensure that introduction of a licensing scheme will act as an effective public protection mechanism.

4. Further information

- 4.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

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