

# Public consultation: Regulation of health practitioners who perform and who advertise non-surgical cosmetic procedures

The Australian Health Practitioner Regulation Agency (Ahpra) and the National Boards are reforming the regulation of registered health practitioners who work in the non-surgical cosmetic procedures sector in Australia to improve practice and standards, public safety, and provide opportunities for more informed consumer choice. Ahpra and the National Boards are consulting on three documents related to the regulation of registered health practitioners who provide and who advertise non-surgical cosmetic procedures:

- Guidelines for nurses who perform non-surgical cosmetic procedures (nurses practice guidelines applies to nurses only)
- 2. Guidelines for registered health practitioners who perform non-surgical cosmetic procedures (shared practice guidelines excluding medical practitioners and nurses), and
- Guidelines for registered health practitioners who advertise non-surgical cosmetic procedures (advertising guidelines – applies to all registered health practitioners).

The three proposed draft guidelines are intended to set out what National Boards expect of registered health practitioners working and advertising in this sector and provide clarity for consumers considering non-surgical cosmetic procedures about the standards expected of practitioners.

As the three proposed draft guidelines are all related to non-surgical cosmetic procedures, Ahpra and the National Boards are consulting on all three guidelines together. Feedback is welcome on any or all of the three draft guidelines.

We welcome feedback from organisations, registered health practitioners and the public.

There are some initial demographic questions and then questions on each of the guidelines we are consulting on. All questions are optional, and you are welcome to respond to any you find relevant, or that you have a view on.

The consultation questions are different in some sections as National Boards are intentionally consulting on the questions most relevant to the professions they regulate.

Your feedback will help us to understand your views and help National Boards set clear standards for registered health practitioners in the non-surgical cosmetic procedures sector, for the protection of the public.

Please email your submission to AhpraConsultation@ahpra.gov.au

Consultation is open for 10 weeks. The submission deadline is close of business 2 February 2024.

## How do we use the information you provide?

The survey is voluntary. All survey information collected will be treated confidentially and anonymously. Data collected will only be used for the purposes described above.

We may publish data from this survey in all internal documents and any published reports. When we do this, we ensure that any personal or identifiable information is removed.

We do not share your personal information associated with our surveys with any party outside of Ahpra except as required by law.

Australian Health Practitioner Regulation Agency
National Boards
GPO Box 9958 Melbourne VIC 3001 Ahpra.gov.au 1300 419 495

The information you provide will be handled in accordance with Ahpra's privacy policy.

If you have any questions, you can contact AhpraConsultation@ahpra.gov.au or telephone us on 1300 419 495.

#### Publication of submissions

We publish submissions at our discretion. We generally <u>publish submissions on our website</u> to encourage discussion and inform the community and stakeholders about consultation responses. Please let us know if you do not want your submission published.

We will not publish on our website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the subject of the consultation. Before publication, we may remove personally identifying information from submissions, including contact details.

We can accept submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. A request for access to a confidential submission will be determined in accordance with the *Freedom of Information Act 1982* (Cth), which has provisions designed to protect personal information and information given in confidence. Please let us know if you do not want us to publish your submission or if you want us to treat all or part of it as confidential.

Published submissions will include the names of the individuals and/or the organisations that made the submission unless confidentiality is expressly requested.

## **Initial questions:**

To help us better understand your situation and the context of your feedback, please provide us with some details about you.

#### Question A

Are you completing this submission on behalf of an organisation or as an individual?

Name of organisation: AbbVie Pty Ltd (Allergan Aesthetics, an AbbVie company)

NB: Allergan Aesthetics, an AbbVie company, develops, manufactures and supplies medical aesthetic products. In Australia, these comprise facial injectable treatments and cryotherapy devices for non-surgical medical aesthetic ('cosmetic') procedures.

As the Regional Medical Director for Allergan Aesthetics, I am responsible for medical affairs across Australia, New Zealand, Asia Pacific, India, Middle East and Africa. In this role, key areas that I lead include patient safety, post-registration research, and scientific information and exchange.

I am also responsible for ensuring the quality and relevance of our extensive, specialised education study program for healthcare professionals working in non-surgical medical aesthetics. In Australia, this medical training is developed and delivered through the Allergan Medical Institute Centre of Excellence in North Sydney.

Excellence in North Sydney.	
Contact email:	
□ Individual	
Name: Click or tap here to enter text.	
Name of organisation: Click or tap here to enter te	<u>kt.</u>
Contact email: Click or tap here to enter text.	

Question B
If you are completing this submission as an individual, are you:
☐ A registered health practitioner?
Profession: Click or tap here to enter text.
□ A consumer / patient?
☐ Other – please describe: Click or tap here to enter text.
□ Prefer not to say
Question C
Do you work in the cosmetic surgery/procedures sector?
□ No
☐ Yes – I perform cosmetic surgery
☐ Yes – I perform cosmetic procedures (e.g. cosmetic injectable such as botulinum toxin and dermal fillers)
∑ Yes – I work in the area but do not perform surgery or procedures (e.g. practice manager, non-clinical employee
□ Prefer not to say
Question D
Do you give permission for your submission to be published?
⊠ Yes, publish my submission <b>with</b> my name/organisation name
☐ Yes, publish my submission <b>without</b> my name
☐ Yes, publish my submission without organisation name
☐ Yes, publish my submission <b>without</b> both my name and organisation name
□ No – <b>do not</b> publish my submission

## Guidelines for nurses who perform non-surgical cosmetic procedures

## **Consultation questions:**

The Nursing and Midwifery Board of Australia (the NMBA) is developing draft nurses practice guidelines at Attachment A of the consultation paper to enable the terminology in the guidelines to be nuanced for nurses, and to delineate the separate roles and scope of enrolled nurses, registered nurses and nurse practitioners in the non-surgical cosmetic procedures sector.

## Question 1:

Is the guidance in the draft nurses practice guidelines appropriate? Why/Why not?

#### Your answer:

As manufacturers and stakeholders committed to ensuring the highest standards of patient care, we endorse and support these guidelines. We advocate for an increased emphasis on patient motivations, thorough assessments, and comprehensive care in the context of non-surgical treatments, especially with the use of Schedule 4 (prescription-only) treatments.

We believe these non-surgical treatments should be approached with a high level of care, diligence, and patient-centred focus at all times.

By aligning with these principles and governed by national regulatory requirements, we aim to enhance the overall safety, efficacy, and patient satisfaction within the field of non-surgical cosmetic procedures.

## Question 2:

Does the guidance in the draft nurses practice guidelines sufficiently inform **nurses** about the NMBA's expectations of nurses (including enrolled nurses (EN), registered nurses (RN) and nurse practitioners (NP) who perform non-surgical cosmetic procedures in Australia? If yes, how? If no, what needs to be changed?

#### Your answer:

We would like to refer to Section 3.1 of the guidelines concerning the consultation requirement for Schedule 4 (prescription-only) cosmetic injectables. We recognise the importance of and fully advocate patient safety and appropriate oversight, we believe guidance should be revised considering practicality and effectiveness of implementation.

The variability in the longevity of non-surgical treatments, particularly those requiring re-treatment every three (3) months, raises some considerations. Having up to four consultations per year, especially when the prescribing medical practitioner or nurse practitioner (NP) is often not the one administering the treatment, could lead to the consultation process becoming less comprehensive and a box-ticking exercise. This in turn, may compromise the quality and effectiveness of a thorough assessment at the time of the consultation.

To address this, we propose an alternative to the guideline that emphasises the importance of a comprehensive consultation that results in a potential 12-month treatment plan. This approach not only accommodates the varying durations of non-surgical treatments but also ensures that patients receive a comprehensive assessment and a more holistic plan that aligns with their treatment goals.

Treatment plans can significantly contribute to patient safety by discouraging 'clinic hopping' or 'clinic shopping,' where overlapping treatments may pose safety risks. By encouraging a treatment plan with clear guidelines for assessing the motivation and expectations of the patient, products involved, and costs associated, there is an opportunity for a higher degree of informed decision-making, with

additional medications prescribed during the treatment plan as deemed necessary by the healthcare professional.

This approach not only streamlines the consultation process but also places overriding emphasis on the patient's safety and well-being, keeping to the spirit of regulations and the need for oversight,

We believe this approach also supports the guidelines outlined in Section 5 - Informed consent including informed financial consent and consent for use of images. By offering a 12-month treatment plan, healthcare professionals can provide detailed information for recommended treatments / non-surgical procedures and the financial implications across the entire period, rather than focusing solely on the cost of individual treatments. This aligns with guidelines' emphasis on providing individuals with enough information to make informed decisions.

This approach to treatment planning will encourage a holistic and comprehensive approach to patient care, (including verbal consent) along with written information provided, enhancing transparency.

#### Question 3:

Does the guidance in the draft nurses practice guidelines sufficiently inform the **public** about the NMBA's expectations of nurses (including enrolled nurses (ENs), registered nurses (RNs) and nurse practitioners (NPs) who perform non-surgical cosmetic procedures in Australia?

#### Your answer:

We would like to highlight considerations that can strengthen patient understanding and ensure transparency in the provision of non-surgical cosmetic procedures.

The descriptor within Section 5.1 states registered health practitioners must provide patients with enough information to help them make an informed decision. Section 5.1a, states patients are to be informed of which cosmetic injectable is being prescribed (type and quantity).

While we recognise the significance of this guiding principle, we wish to draw attention to the term 'Type', which might be interpreted as providing a generic or category name without specifying the brand. This approach could impede patients' ability to make fully informed decisions given the inherent differences among various Schedule 4 injectables. These injectables undergo distinct manufacturing processes and formulations, resulting in significant variations in clinical performance, including duration, dose, effectiveness and safety profiles, all influencing outcomes, and the overall patient experience.

For instance, the longevity of effects can significantly differ between brands, impacting the frequency of required treatments. Furthermore, the outcomes achieved, such as the degree of correction or enhancement, may vary based on the specific product used. It is important to note that these injectables are not interchangeable, as they are tailored to different patient needs and desired outcomes.

Awareness of the brand name of the scheduled injectable is imperative for ensuring informed consent. Beyond meeting regulatory requirements, it facilitates comprehensive discussions between practitioners and patients regarding the unique characteristics, potential risks, and benefits associated with the chosen product. This knowledge is equally critical for appropriate post-treatment care, enabling healthcare professionals to address specific considerations related to the selected brand and enhance overall patient safety and outcomes.

Furthermore, it should also be noted that while botulinum toxins are a class of prescription-only medicines of which there are currently four TGA approved toxins, the brand name BOTOX® (onabotulinum toxin type A) is frequently used to refer to the class of injectable toxins and generic descriptor for toxin treatment. BOTOX® is trademarked and a specific brand of botulinum toxin type A, and therefore should not be used to generically to describe all types, products or brands of botulinum toxin products available. This is particularly important because as detailed above, not all botulinum toxin type A products are the same. Using the brand name BOTOX® incorrectly not only is misleading but could pose a patient safety risk should a patient experience an adverse event.

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We propose an addition to guidelines, specifying patients be informed of the specific brand name of the product they are receiving.

In the context of cosmetic injectables, it is also important to note that not all toxins or dermal fillers approved for use in Australia are indicated for the same treatment areas, yet all brands are regularly used off-label (or experimental).

As with other prescription medicines, we recommend reinforcing existing guidelines by stating health practitioners and nurses should use a product registered / approved for the relevant indications before considering using a product without a registered indication.

Additionally, if off-label (or experimental) use is considered, practitioners should inform the patient about the use of a product with an unapproved indication and provide clear clinical reasons for doing so

#### Question 4:

In section 4.2, the draft nurses practice guidelines propose that 'the registered nurse and/or the nurse practitioner must consider the clinical appropriateness of the cosmetic procedure for a person who is under the age of 18 years. The NMBA considers that botulinum toxin and dermal fillers should not be prescribed for persons under the age of 18 for cosmetic purposes.'

Is this information clear? If not, why not?

#### Your answer:

We support that cosmetic injectable treatments such as botulinum toxin and dermal fillers are only prescribed for those aged 18 years and over, when they are legally considered an adult. The registered nurse and / or the nurse practitioner must consider the clinical appropriateness of the treatment.

#### Question 5:

Is there anything further you believe should be included in section 4?

#### Your answer:

#### Question 6:

In section 8.1, the draft nurses practice guidelines propose 'the RN/NP is responsible for ensuring that any other person's participating in the person's care or treatment have appropriate education, training and competence, and is adequately supervised as required'.

Is this a reasonable requirement? If yes, why? If not, why not?

#### Your answer:

The following considerations are regarding the current language used in Sections 8 and 10 of the guidelines. Specifically those addressing the provision of care / treatment and the education and experience requirements for practitioners involved in the administration of non-surgical cosmetic procedures.

While we support the inclusion of guidelines emphasising appropriate education, training, and competence, we believe the term 'appropriate education, training, and competence' should be further clarified and defined.

All healthcare professionals seeking to achieve high standards of quality and safety in non-surgical procedures, such as injectables, should be provided with a clear training framework. For example, sections 8 and 10 of the guidelines, do not currently outline minimum universal standards across these professions, thereby increasing the risk to both patients and practitioners.

We recommend guidelines be revised to clarify the diversity of competencies and knowledge required to uphold high professional and clinical standards in the administration of non-surgical procedures, particularly with injectable treatments and outline clear and measurable standards.

To support professional development in non-surgical cosmetic procedures such as injectables, Allergan Aesthetics provides learning content tailored to different levels of experience through the Allergan Medical Institute (AMI).

The AMI provides free of charge online (on-demand and live) and face-to-face educational content from entry to advanced injector level, covering the complexities of facial anatomy and the intricacies of injection techniques to minimise the risk of adverse events. Integral to the curriculum are learning outcomes to ensure participants can identify and manage complications, and when and how to escalate to other professional staff or services.

Our commitment to training and education is demonstrated by our investment in the established Allergan Medical Institute Centre of Excellence based in Sydney, where our skilled training team and clinical experts provide a structured educational framework for the Australian aesthetic medicine professional community.

The AMI model is well recognised for providing these highly valued courses, which are informed by current scientific evidence base and clinical best practice. We see this as an extremely important part of our participation in the Australian marketplace and hence Allergan Aesthetics supports the recommendation that the RN is responsible for ensuring that any other person/s participating in the person's care or treatment have appropriate education, training and competence, and is adequately supervised as required.

## Question 7:

In section 16.1, the draft nurses practice guidelines propose 'that RNs first practise for a minimum of one-year full-time equivalent post initial registration, to consolidate the foundational skills and knowledge as an RN in a general or specialist area of nursing practice (not in the area of non-surgical cosmetic procedures). RNs who perform non-surgical cosmetic procedures are required to undertake detailed assessment and planning of care, have complex anatomical and physiology knowledge as well as decision-making relating to pharmacodynamics and pharmacokinetics'.

Is the guidance proposed a reasonable requirement? If not, why not?

## Your answer:

Please refer to response to question 6

### **Question 8:**

Is there any further detail that needs to be included in the draft nurses practice guidelines to ensure public safety? If yes, please provide details.

#### Your answer:

On page 11 of the consultation document, it states The Medical Board's guidelines specify a validated psychological screening tool must be used to screen patients for BDD only when they are seeking cosmetic surgery. Like the Medical Board's guidelines, these draft guidelines do not require that a validated screening tool be used for patients seeking non-surgical cosmetic procedures. The requirement is that an assessment occur, and a referral for further evaluation, if indicated. However, in Section 2.2 of the guidelines for both nurse practitioners and other Health practitioners, it states that they must assess the person using an evidenced-based and validated assessment tool for underlying psychological conditions such as body dysmorphic disorder (BDD), which may make them an unsuitable candidate for the procedure.

We would recommend this discrepancy within the consultation document be clarified and amended to confirm whether a validated tool or assessment is completed for BDD during the patient consultation process.

In Section 5.1a, it includes the designation of whether the procedure is new or 'experimental.' We recommend considering an alternative terminology for 'experimental' which is less alarmist. Perhaps consider replacing with 'off label' or an 'unapproved indication'.

Guidelines for registered health practitioners who perform non-surgical cosmetic procedures.

## **Consultation questions:**

The proposed draft shared practice guidelines (at Attachment B of the consultation paper) will apply to all registered health practitioners, except for medical practitioners (who are already subject to the Medical Board of Australia's (the MBA) *Guidelines for registered medical practitioners who perform cosmetic surgery and procedures*) and nurses (who will be required to comply with the draft *Guidelines for nurses who perform non-surgical cosmetic procedures*, if approved).

#### Question 9:

Is the guidance in the draft shared practice guidelines appropriate? Why/why not?

#### Your answer:

Allergan Aesthetics support the importance of setting standards to ensure safe and effective non-surgical cosmetic procedures, however, are apprehensive of the broad application of guidelines to all registered health practitioners, as listed in the document. The inclusivity of health practitioners such as Aboriginal and Torres Strait Islander Health Practitioners, Chinese Medicine Practitioners, chiropractors, occupational therapists, optometrists, osteopaths, paramedics, pharmacists, physiotherapists, podiatrists, and psychologists raise concerns about the potential risks to patient safety.

Non-surgical cosmetic procedures require specialised knowledge and skills, and not all health practitioners listed may have the specific education or training necessary to safely administer these treatments and manage any complications that may possibly arise. We believe that guidelines should consider HCP education pathway and qualifications, to ensure a minimum safety for patients.

We propose careful consideration be given to tailoring guidelines specifically to health practitioners whose scope of practice is closely related to non-surgical cosmetic treatments and who have had specific and appropriate training in non-surgical cosmetic procedures. This targeted approach will help ensure practitioners with the appropriate education and training are the primary contributors to the safe and effective delivery of non-surgical cosmetic procedures, minimising potential risk to patients.

## Question 10:

Does the guidance in the draft shared practice guidelines sufficiently inform registered health practitioners about National Boards' expectations when performing non-surgical cosmetic procedures in Australia? Yes/No. If no, what needs to be changed?

## Your answer:

We would like to refer to Section 3.1 of the guidelines concerning the consultation requirement for Schedule 4 (prescription only) cosmetic injectables. Allergan Aesthetics recognise the importance of and advocate patient safety and appropriate oversight and recommend amendments to this section considering practicality and the proposed guideline.

The variability in the longevity of non-surgical treatments, particularly those requiring re-treatment every three (3) months, should be considered. Having up to four consultations per year, especially when the prescribing medical practitioner or nurse practitioner (NP) is often not the one administering the treatment, could lead to the consultation process becoming less comprehensive and a box-ticking exercise. This in turn, may compromise the quality and effectiveness of a thorough assessment at the time of consultation.

To address this concern, we propose an alternative guideline with emphasis on the importance of a comprehensive consultation that results in a potential 12-month treatment plan. This approach not only accommodates the varying durations of non-surgical treatments but also ensures that patients receive a comprehensive assessment and more holistic plan that aligns with treatment goals.

Treatment plans can significantly contribute to patient safety by discouraging 'clinic hopping' or 'clinic shopping' where overlapping treatments may pose safety risks. By encouraging a treatment plan with clear guidelines for assessing the motivation and expectations of the patient, products involved, and costs associated, there is an opportunity for more informed decision-making. Additional medications can be prescribed during the treatment plan, as deemed necessary by the healthcare professional.

This approach not only streamlines the consultation process but also places overriding emphasis on the patient's safety and well-being, keeping to the spirit of regulations and the need for oversight.

We believe this approach also supports the guidelines outlined in Section 5 - Informed consent including informed financial consent and consent for use of images. By offering a 12-month treatment plan, healthcare professionals can provide detailed information for recommended treatments / non-surgical procedures and the financial implications across the entire period, rather than focusing solely on the cost of individual treatments. This aligns with guidelines' emphasis on providing individuals with enough information to make informed decisions.

This approach to treatment planning will encourage a holistic and comprehensive approach to patient care, (including verbal consent) along with written information provided, enhancing transparency.

## Question 11:

Is the guidance in the draft shared practice guidelines useful for the **public** to understand National Boards' expectations of registered health practitioners who perform non-surgical cosmetic procedures in Australia? Yes/No. If no, what would be more helpful?

#### Your answer:

Further action can be taken to strengthen patient understanding and ensure transparency in the provision of non-surgical cosmetic procedures.

The descriptor within Section 5.1 states registered health practitioners must provide patients with enough information to help them make an informed decision. Section 5.1a, states patients are to be informed of which cosmetic injectable is being prescribed (type and quantity).

While we recognise the significance of this guiding principle, we wish to draw attention to the term 'Type,' which might be interpreted as providing a generic or category name without specifying the brand. This approach could impede patients' ability to make fully informed decisions, particularly given the inherent differences among various Schedule 4 injectables. Each product will undergo a distinct manufacturing process with varying formulations, resulting in significant variations in clinical performance, including duration, dose, effectiveness and safety profile, all influencing outcomes and the overall patient experience.

For instance, the longevity of effects can significantly differ between brands, impacting the frequency of required treatments. Furthermore, the outcomes achieved, such as the degree of correction or enhancement, may vary based on the specific product used. It is important to note that these injectables are not interchangeable, as they are tailored to different patient needs and desired outcomes.

Understanding the brand name of the scheduled injectable becomes imperative for ensuring informed consent. Beyond meeting regulatory requirements, it facilitates comprehensive discussions between practitioners and patients regarding the unique characteristics, potential risks, and benefits associated with the chosen product. This knowledge is equally critical for proper post-treatment care, enabling healthcare professionals to address specific considerations related to the selected brand and enhance overall patient safety and satisfaction.

Furthermore, it should also be noted that while botulinum toxins are a class of prescription-only medicines of which there are currently four TGA approved toxins, the brand name BOTOX® (onabotulinum toxin type A) is frequently used to refer to the class of injectable toxins and used as a generic descriptor for either administering or receiving toxin treatment.

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BOTOX® is trademarked and a specific brand of botulinum toxin type A, and therefore should not be used to generically to describe all types of botulinum toxin products that are available. This is particularly important because as detailed above, not all botulinum toxin type A products are the same. Using the brand name BOTOX® incorrectly not only is misleading but could pose a patient safety risk should a patient experience an adverse event.

We propose an addition to the guidelines, specifying that patients should be informed of the specific brand name of the product they are receiving.

In the context of cosmetic injectables, it is also important to note that not all toxins and dermal fillers approved for use in Australia are indicated for the same treatment areas, yet all brands are regularly used off-label (or experimentally).

As with prescription medicines, we recommend reinforcing the existing guidelines by stating that health practitioners and nurses should use a product registered / approved for the relevant indications before considering using a product without a registered indication.

Additionally, if off-label (or experimental) use is considered, practitioners should inform the patient about the use of an unapproved indication and provide clear clinical reasons for doing so.

## Question 12:

Is there anything you believe should be added to or removed from the definition of 'non-surgical cosmetic procedures' as it currently appears in the draft shared practice guidelines?

What changes do you propose and why?

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## Question 13:

The draft shared practice guidelines propose a set of consistent requirements for practitioners practising in this sector.

Do you think it's appropriate for consistent requirements to apply to all practitioners practising in this sector regardless of their profession? Or do you think there are variations, additions or exclusions required for a particular profession or professions?

What changes do you propose and why?

## Your answer:

Non-surgical cosmetic procedures require specialised knowledge and skills, and not all health practitioners listed in this guideline may have the specific education and training necessary to safely administer these treatments and manage any complications that may possibly arise. We believe that guidelines should consider HCP education pathway and qualifications, to ensure a minimum safety for patients.

We propose careful consideration be given to tailoring guidelines specifically to health practitioners whose scope of practice is closely related to non-surgical cosmetic treatments and who have had specific and appropriate training in non-surgical cosmetic procedures. This targeted approach will help ensure practitioners with the appropriate education and training are the primary contributors to the safe and effective delivery of non-surgical cosmetic procedures, minimising potential risk to patients.

## Question 14:

While it is acknowledged that many people who seek non-surgical cosmetic procedures do not have an underlying psychological condition such as body dysmorphic disorder (BDD), the Medical Board of Australia's practice guidelines and the Nursing and Midwifery Board of Australia's proposed guidelines require medical practitioners and nurses who perform the cosmetic procedure or prescribe the cosmetic injectable, to assess their patients for underlying psychological conditions, such as BDD.

Is this a reasonable requirement of other registered health practitioners performing cosmetic procedures as well? If yes, why? If not, why not?

#### Your answer:

On page 11 of the consultation document, it states The Medical Board's guidelines specify that a validated psychological screening tool must be used to screen patients for BDD only when they are seeking cosmetic surgery. Like the Medical Board's guidelines, these draft guidelines do not require that a validated screening tool be used for patients seeking non-surgical cosmetic procedures. The requirement is that an assessment occur, and a referral for further evaluation, if indicated. However, in Section 2.2 of the guidelines for both nurse practitioners and other Health practitioners, it states that they must assess the person using an evidenced-based and validated assessment tool for underlying psychological conditions such as body dysmorphic disorder (BDD), which may make them an unsuitable candidate for the procedure.

We would recommend this discrepancy within the consultation document be clarified and amended so is clear as to whether a validated tool is required for non-surgical treatments.

## Question 15:

Is there any further detail that needs to be included in the draft shared practice guidelines to ensure public safety? If yes, please provide details.

## Your answer:

The following considerations are in regard to the current language used in Sections 8 and 10 of the guidelines, specifically addressing the provision of care / treatment and the education and experience requirements for those practitioners involved in the administration of non-surgical cosmetic procedures.

While we support the inclusion of guidelines emphasising appropriate education, training, and competence, we believe the term 'appropriate education, training, and competence' should be further clarified and defined.

All healthcare professionals seeking to achieve high standards of quality and safety in non-surgical procedures, such as injectables, should be provided with a clear training framework. For example, Sections 8 and 10 of the guidelines, do not currently outline minimum universal standards across these professions, thereby increasing the risk to both patients and practitioners.

We recommend guidelines be revised to clarify the diversity of competencies and knowledge required to uphold high professional and clinical standards in the administration of non-surgical procedures, particularly with injectable treatments and outline clear and measurable standards.

To support professional development in non-surgical cosmetic procedures such as injectables, Allergan Aesthetics provides learning content tailored to different levels of experience through the Allergan Medical Institute (AMI).

The AMI provides free of charge online (on-demand and live) and face-to-face educational content from entry to advanced injector level, covering the complexities of facial anatomy and the intricacies of injection techniques to minimise the risk of adverse events. Integral to the curriculum are learning outcomes to ensure participants can identify and manage complications, and when and how to escalate to other professional staff or services.

Our commitment to training and education is demonstrated by our investment in the established Allergan Medical Institute Centre of Excellence based in Sydney, where our skilled training team and clinical experts provide a structured educational framework for the Australian aesthetic medicine professional community.

The AMI model is well recognised for providing these highly valued courses, which are informed by the current scientific evidence base and clinical best practice. We see this as an extremely important part of our participation in the Australian marketplace and hence Allergan Aesthetics supports the recommendation that the RN is responsible for ensuring that any other person/s participating in the person's care or treatment have appropriate education, training and competence, and is adequately supervised as required.

## Guidelines for registered health practitioners who advertise non-surgical cosmetic procedures

# **Consultation questions:**

The proposed draft advertising guidelines (at Attachment C of the consultation paper) will apply to all registered health practitioners who advertise non-surgical cosmetic procedures.

## Question 16:

Is the guidance in the draft advertising guidelines appropriate? Why/why not?

Your answer:

## Question 17:

Does the guidance in the draft advertising guidelines sufficiently inform **registered health practitioners** about National Boards' expectations when advertising non-surgical cosmetic procedures? Yes/No. If no, what needs to be changed?

## Your answer:

These guidelines will play a crucial role in transparency between practitioner and patient, and high standards of patient care within the field.

We recommend the inclusion of a specific reference within guidelines reinforcing the expectation healthcare professionals (HCPs) comply with relevant Australian legislation and codes of conduct, such as the Therapeutic Goods Advertising Code (TGAC). This consideration should extend to the responsibilities of pharmaceutical and medical device manufacturers / distributors operating in accordance with their respective industry codes of conducts.

We feel it important to raise the recent move from the TGA to ban the use of terms to generically describe anti-wrinkle injections and dermal fillers in any advertising of a clinic's or practitioner's services.

Prohibiting the use of general terms to describe these treatments or services, may create greater confusion among patients seeking information on non-surgical cosmetic treatments and procedures and as a result, may potentially compromise patient safety.

Furthermore, given the wide array of diverse non-surgical cosmetic treatments and procedures available to patients seeking medical aesthetic treatments - as well as the various clinical performance, duration, outcomes and safety profile of each - it is important that patients are aware of the category type available when provided with advertised content in order to make a well-informed decision and consent to injectable treatment.

As stated in the draft advertising guidelines (pg. 40) 'Advertising that is ethical, honest, and responsible helps to keep people safe by providing them with accurate and balanced information that can be used to make informed decisions.' We strongly support this tenet and believe there is a way for HCPs to ethically inform and educate about non-surgical cosmetic treatments and procedures in their communication practices including advertising, which contributes to a more cohesive and compliant healthcare landscape, where patient safety is at the core.

#### Question 18:

Is the guidance in the draft advertising guidelines useful for the <b>public</b> to understand National Boards' expectations of registered health practitioners who advertise non-surgical cosmetic procedures in Australia? Yes/No. If no, what would be more helpful?
Your answer:
Question 19:
Is there any further detail that needs to be included in the draft advertising guidelines to ensure public safety? If yes, please provide details.
Your answer:
The definition of 'non-surgical cosmetic procedures' in the draft advertising guidelines includes examples of what are considered non-surgical cosmetic procedures and includes procedures that are restricted to the practice of registered health practitioners as well as procedures that may be performed by people who are not registered health practitioners. This decision was made to promote consistency between the various guidelines which regulate both the practice and advertising of non-surgical cosmetic procedures and cosmetic surgery.
Question 20:
Is the definition of 'non-surgical cosmetic procedures' in the draft advertising guidelines appropriate when setting standards for the advertising of non-surgical cosmetic procedures by regulated health practitioners? Why/why not?
Your answer:
Question 21:
Is there anything you believe should be added to or removed from the definition of 'non-surgical cosmetic procedures' as it currently appears in the draft advertising guidelines?
What changes do you propose?
Your answer:
About IV infusion treatments:

Ahpra and the National Boards are aware of concerns about the advertising of IV infusion treatments and have issued previous statements in relation to this. IV infusions, like non-surgical cosmetic procedures, are invasive procedures with inherent health and safety risks for patients.

While IV infusion treatments are not strictly a non-surgical cosmetic procedure, many advertisers quote their patients as looking or feeling better after an infusion. Ahpra takes the view that there is little or no accepted evidence to support such generalised claims, and that claims about general improvements in health, wellness, anti-ageing or appearance are therefore misleading and in breach of the National Law. As with any regulated health service claims made about the benefits of IV infusions must be accurate and not misleading. This is because consumers are likely to rely on purported scientific claims and be significantly influenced by such claims, when making health care choices.

While these draft guidelines are focused on the advertising of non-surgical cosmetic procedures, we welcome feedback on whether separate guidelines should be developed in relation to the advertising of IV infusion treatments.

## Question 22:

Do you support the development of separate guidelines in relation to the advertising of IV infusion treatments? Why/why not?
Your answer:
Question 23:
If you support the development of separate guidelines in relation to the advertising of IV infusion treatments, what do you believe should be contained within these guidelines?
Your answer:
Question 24:
Do you have any other feedback about the draft practice guidelines and draft advertising guidelines for non-surgical cosmetic procedures?
Your answer: