

**Are you making a submission as?**

- An organisation

**Do you work in the cosmetic surgery/procedures sector?**

- Yes – I work in the area but do not provide surgery or procedures (e.g. practice manager, non-clinical employee).

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

NB: Allergan Aesthetics, an AbbVie company, develops, manufactures and supplies medical aesthetic products; in Australia, this comprises facial injectable treatments and cryotherapy devices for minor procedures. We also provide extensive training, detailed in this submission, on safe and effective use of our products as part of our commitment to Quality Use of Medicines.

**For medical practitioners, what type of medical registration do you have?**

- N/A

**Do you give permission to publish your submission?**

- Yes, with my name

# Feedback on draft Registration standard

This section asks for feedback on the *Draft Registration standard: Endorsement of registration for cosmetic surgery for registered medical practitioners*.

The details of the requirements for endorsement are in the [draft registration standard](#).

**1. Are the requirements for endorsement appropriate?**

N/A

**2. Are the requirements for endorsement clear?**

N/A

**3. Is anything missing?**

N/A

# Feedback on draft revised Cosmetic Guidelines

This section asks for feedback on the Board's proposed changes to its 2016 *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures*.

The details of the revised guidance are in the [draft revised Cosmetic Guidelines](#).

## 4. Are the proposed changes to the Cosmetic Guidelines appropriate?

Allergan Aesthetics, an AbbVie Company, supports regular review of professional guidelines for medical practitioners providing aesthetic ('cosmetic') medical procedures, so that they are informed by current clinical evidence, high training standards and regulatory reforms, thereby providing a strong foundation for consumer protection in line with the principles of Quality Use of Medicines and Medicine Safety in what is a rapidly evolving field of practice.

In Australia, our company provides products, education and support relating only to several TGA-approved non-surgical aesthetic medical procedures, so we have focused our comments on the relevant parts of the draft proposed guidelines, primarily aspects we believe are important to highlight in the section headed: 'Providing minor (non-surgical) cosmetic medical procedures' (pp. 10-14 inclusive).

Our primary recommendation is for the Medical Board of Australia (MBA) and/or Australian Medical Council (AMC) to establish a separate, dedicated standard of structured training and education to guide and support medical practitioners conducting (or considering conducting) non-surgical ('minor') aesthetic ('cosmetic') medical procedures in Australia to achieve a high level of professional and clinical practice in their field.

In parallel to the work being done now by the AMC to develop benchmark accreditation standards and graduate outcomes for medical practitioners conducting surgical ('major') cosmetic medical procedures, a significant opportunity exists to develop a similar training framework for those conducting 'non-surgical ('minor') aesthetic medical procedures.

Additional stakeholder advice on a dedicated draft training standard for 'minor' procedures would be advisable and should involve consulting professional bodies that represent those medical practitioners who will be impacted.

As a pioneer in developing aesthetic medicines and devices, we have provided what we believe to be the most comprehensive medical educational offerings in Australia for 20 years, training medical practitioners in the unique skills and knowledge required to proficiently and safely conduct non-surgical aesthetic medical procedures. We are clear that injectable treatments (dermal fillers and botulinum toxin) are prescription-only medical procedures in Australia, and

as such, they should only be performed by a trained and qualified medical practitioner, in an appropriate clinical environment that is fully compliant with relevant government and industry regulations.

To support professional development, we provide learning content that is tailored to different levels of experience from entry level to advanced and covers the complexities of facial anatomy and the intricacies of injection techniques to minimise risks 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 new Allergan Medical Institute Centre of Excellence based in Sydney, where our training team and clinical experts provide a structured educational framework for those in the Australian aesthetic medicine professional community. The Allergan Medical Institute is globally recognised for providing these highly valued courses both online and face to face and we see this as an extremely important part of our participation in the Australian marketplace.

## 5. Does splitting the guidance into sections for major and for minor cosmetic procedures make the guidance clearer?

The proposed draft provided by the Board improves clarity to the extent that it distinguishes the two distinct groups of procedures ('major' vs 'minor') and we strongly support providing tailored guidelines in two separate sections, as this not only makes the document easier to navigate but also, importantly, recognises that there are specific and very different competencies and skills necessary to practice within either one to a high professional and clinical standard.

We do feel, however, as indicated above, that there is a gap for a structured training pathway for medical practitioners conducting or wishing to conduct 'minor' procedures. Whether they are operating solely in this area or are also conducting surgery, this group of medical practitioners should be supported by a clear training framework to meet the proposed requirement for 'appropriate knowledge and training in specific cosmetic procedures being offered' (10.1), which is currently undefined and therefore open to interpretation and therefore carries risks for both medical practitioners and patients.

In addition, we feel the terminology of 'minor' and 'major' should be re-considered. An alternative approach, which is used in other jurisdictions, is to differentiate the two groups as simply 'surgical' and 'non-surgical'.

- There are several reasons for this recommendation: We believe labelling non-surgical procedures as 'minor' does not acknowledge the specific skills and knowledge required in order for medical practitioners to safely and proficiently practice in this area, and may unintentionally downplay the risks attached to those that are medical in nature including injections
- Furthermore, we believe that the term 'minor' also does not recognise the significant value that non-surgical procedures have been shown in a growing body of research to provide to patients. Importantly, over and above the more common motivations for their use, non-surgical procedures are increasingly supporting people who seek transformational change, for instance following injury or trauma, in reassigning gender or otherwise reflecting their identity. To consult effectively with these individuals – or any patient – and to meet their expectations and often complex needs, medical practitioners must be able to conduct considered, individualised assessments of suitability, as well as execute highly technical clinical techniques in line with a bespoke treatment plan. This requires a high level of training and skill that it would be unfair to characterise as 'minor' - and certainly these patients do not view the process or impact this way.

**6. Are the draft Cosmetic Guidelines and the Board's expectations of medical practitioners clear?**

In addition to our recommendation regarding stated and defined standards for 'appropriate knowledge and training in specific cosmetic procedures being offered' (Minor Procedures 10.1), we highlight the following additional ambiguities in the draft:

**Minor (non-surgical) - 2.0 'Assessment of suitability'**

In line with our recommendation, a structured training program aligned with the skill level of those medical practitioners conducting minor cosmetic procedures should incorporate training and learning outcomes for conducting a full assessment of a patient's suitability for the procedure and how to determine when a referral is required.

**Minor (non-surgical) - 4.0 'Under 18s'**

Allergan Aesthetics' products (facial injectable treatments and cryotherapy devices) are not approved for use in patients under the age of 18. We do not recommend the use of any of our products outside the indications in the TGA-approved Australian Product Information / Directions for Use.

**7. Do you support the requirement for a GP referral for all patients seeking major cosmetic surgery?**

N/A

**8. Do you support the requirement for major cosmetic surgery to be undertaken in an accredited facility?**

N/A

**9. Is anything missing?**

As stated in our above responses, Allergan Aesthetics believes the guidelines could convey a greater recognition of the value that medical practitioners working in non-surgical aesthetic medical procedures bring every day to their patients and acknowledge the many beneficial reasons so many choose to undergo these treatments. With the vast majority of procedures conducted in Australia achieving high levels of patient satisfaction, we are committed to supporting industry reforms that maintain and improve on these outcomes.

# Feedback on draft Advertising Guidelines

This section asks for feedback on guidelines for advertising cosmetic surgery.

The Board's current *Guidelines for medical practitioners who perform cosmetic medical and surgical procedures* (2016) include a section on 'Advertising and marketing'.

The Board is proposing standalone *Guidelines for medical practitioners who advertise cosmetic surgery* because of the influential role of advertising in the cosmetic surgery sector.

The details of the advertising guidance are in the [draft Advertising Guidelines](#).

## 10. Is the guidance in the draft Advertising Guidelines appropriate?

N/A

## 11. Are the draft Advertising Guidelines and the Board's expectations of medical practitioners clear?

N/A

## 12. Is anything missing?

N/A



## Additional comments

13. Do you have any other comments about cosmetic surgery regulation?

N/A