Australian Government
Department of Health

Deputy Secretary

Mr Andrew Brown
Lead Reviewer
Independent review of the regulation of health practitioners in cosmetic surgery
CSReview@ahpra.gov.au

Dear Mr Brown

Please find attached the Therapeutic Goods Administration (TGA) submission to the independent review of the regulation of health practitioners in cosmetic surgery. The TGA is the part of the Department of Health responsible for the regulation of therapeutic goods, including medicines and medical devices. Our submission describes the interactions between therapeutic goods and the clinical practice of cosmetic surgery.

I appreciate the opportunity for the TGA to provide a submission to your review and thank you for the timeframe extension to produce a considered and hopefully informative contribution. I understand you have received many submissions and look forward with interest to the outcomes of the review. The TGA also welcomes opportunities for ongoing collaboration between the TGA and Ahpra.

The TGA is available to help further with your review and to meet to clarify content in this submission or to provide any additional detail. The Department's contact officer is [redacted], First Assistant Secretary, Medical Devices and Product Quality Division (P: [redacted], E: [redacted]).

Yours sincerely

[redacted]

Adj. Professor John Skerritt
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2 May 2022

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Australian Government

Department of Health
Therapeutic Goods Administration

Therapeutic Goods Administration (TGA) response to the Australian Health Practitioner Regulation Agency (Ahpra) and Medical Board of Australia (MBA) Independent review of the regulation of health practitioners in cosmetic surgery

May 2022

Contents

Executive Summary

While the TGA does not regulate the clinical practice of health professionals, there is significant potential for interaction around the regulation of therapeutic goods used in cosmetic surgery. This may be relevant throughout the regulatory lifecycle of medical devices, particularly in post market monitoring, advertising, and compliance requirements for therapeutic goods.

The TGA notes a range of issues for therapeutic goods relevant to cosmetic surgery:

- **Post market issues** for cosmetic surgery products, including:
  - breast implants, including encouraging all plastic, reconstructive, cosmetic, and general breast surgeons to contribute to the Australian Breast Device Register
  - cometic procedures, including potential deceptive health claims and continuing concerns about products such as cosmetic injectables.
- Use of **unapproved products**, noting that use of an unapproved product is a clinical decision for the health practitioner
- **Off-label use** of therapeutic goods, noting off-label use is a clinical decision made at the discretion of the treating clinician
- Potential **adverse event mandatory reporting for health facilities**, noting that this proposal would include many facilities where cosmetic surgery is undertaken
- Changes to require **patient product information** (Patient Implant Cards and Patient Information Leaflets) for implantable medical devices, including encouraging surgeons and health care facilities to pass this information to patients
- Potential changes to **regulate products without a medical intended purpose**, which if implemented will impact the regulatory oversight of these devices used in cosmetic surgery
- **Emerging medical device technologies**, noting production and use of custom or personalised medical devices are often beyond the scope of clinical practice oversight, and also may be outside the scope of the normal professional insurances associated with clinical practice. Additional changes are also in place for software as a medical device, and emerging manufacturing technologies such as 3D printing may also have future impacts.

In responding to the consultation questions, feedback is provided on the following issues:

- **Code and Guidelines:** suggesting therapeutic goods issues on patient information materials, adverse event reporting, improved informed consent about long-term risks with implants, stronger ongoing clinical oversight for implants, off-label use, unapproved products, and training might be covered in the guidelines
- **Management of notifications:** noting that some reports on surgeon performance may also have associated therapeutic goods adverse events which should also be reported
- **Advertising restrictions:** noting advertising requirements also apply under therapeutic goods regulation (as outlined in existing Ahpra guidelines)
- **Title protection and endorsement for approved areas of practice:** noting that the safety and performance of therapeutic goods used in cosmetic surgery rely heavily on the skills, training, and competency of the health practitioners involved in the surgery

- **Cooperation with other regulators:** referral of issues between the TGA and Ahpra can occur on an ad hoc basis, and there is potential for joint investigation and compliance action where appropriate
- **Facilitating mandatory and voluntary notifications:** noting introduction of medical device mandatory reporting for health facilities will capture procedures by cosmetic surgeons, and mutual exchange of information (and possible joint investigations) may be helpful
- **Information to consumers:** The TGA is aware that informed consent is not always effective for cosmetic surgery procedures, and have a range of tools to support informed consent

Introduction

The Department of Health, through the Therapeutic Goods Administration (TGA), regulates the supply, import, export, manufacturing, and advertising of therapeutic goods to ensure that therapeutic goods available for supply in Australia are safe and fit for their intended purpose.

While the direct regulation of cosmetic surgery health practitioners is beyond the TGA's remit, a range of 'therapeutic goods' used in the practice of cosmetic surgery are regulated by the TGA.

The comments provided in this submission are limited to issues relevant to the regulation of therapeutic goods. As a result, this submission does not fully address all the questions posed by the consultation paper, focusing on elements relevant to the therapeutic goods regulatory framework.

What are therapeutic goods?

The TGA regulates therapeutic goods, which are products which are for therapeutic use.
'Therapeutic use' means use for:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
- influencing, inhibiting or modifying a physiological process in persons; or
- testing the susceptibility of persons to a disease or ailment; or
- influencing, controlling or preventing conception in persons; or
- testing for pregnancy in persons; or
- the replacement or modification of parts of the anatomy in persons. [1]

The TGA does not regulate the clinical practice of health professionals. However therapeutic goods – primarily medicines and medical devices – are used by health practitioners in their practice, including cosmetic surgeons. Some will be products with clear cosmetic uses, such as breast implants, dermal fillers, intense pulsed-light devices, liposuction systems, etc. Others will not be cosmetic products but will still be critical to the cosmetic surgery procedure, such as anaesthetic and pain medications, surgical instruments, operating theatre equipment, sutures, etc.

[1] For full definitions of 'therapeutic good' and 'therapeutic use', refer to *Therapeutic Goods Act 1989*, s.3

It is noted that the Ahpra review is focused on 'cosmetic surgery' (*i.e.,* involving cutting beneath the skin) such as breast augmentation, breast reduction, rhinoplasty, surgical face-lifts and liposuction, while 'minor cosmetic procedures' (including those which may pierce the skin, such as injectables) are out of scope for this review. For this reason, much of the commentary below focuses on certain medical devices intended for use in cosmetic surgery. A range of other therapeutic goods are also used in cosmetic surgery, including medicines and more general medical devices, but this use is generally not significantly different for cosmetic surgery than for other surgical procedures.

Products used in cosmetic surgery may also be subject to a number of other regulatory frameworks.

Regulatory regimes which may apply to cosmetic products

Several regulatory regimes may apply to cosmetic products:

- **Cosmetic ingredient regulation:** Cosmetic ingredients are managed under the *Industrial Chemicals Act 2019* which defines what a 'cosmetic' is and that a product cannot be a cosmetic if it is a therapeutic good. The Australian Industrial Chemicals Introduction Scheme (AICIS) undertakes the risk assessment of ingredients used in cosmetic products. AICIS regulates chemicals that are imported or manufactured for industrial use including in cosmetics. Given the focus on ingredients for cosmetic products, this scheme falls outside the scope of the Ahpra review.
- **Cosmetic product regulation:** Through the administration of the Australian Consumer Law (ACL) the Australian Competition and Consumer Commission (ACCC), and state and territory consumer protection regulators, aim to minimise the risk posed by unsafe consumer goods that are not regulated under a specialist regime, such as therapeutic goods. This includes administering a mandatory information standard for cosmetic ingredient labelling. The ACL also contains provisions that prohibit false and misleading claims.
- **Therapeutic goods regulation:** Cosmetic products are not routinely regulated by the TGA but may be regulated where they are 'therapeutic goods'. Whether a cosmetic product is also a therapeutic good will be based on:
  - the primary use
  - the ingredients
  - the claims made
  - overall presentation and context
  - regulatory controls

Background

Regulation of therapeutic goods

Premarket approval required: Therapeutic goods – primarily medicines, biologicals and medical devices – must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully imported, exported, supplied or advertised in Australia, unless an exemption applies. Health practitioners, including cosmetic surgeons, should ensure all therapeutic goods used in their practice are appropriately entered in the ARTG. This can generally be checked with the product

supplier in the first instance. Where directly importing or manufacturing therapeutic goods the health practitioner may be required to meet therapeutic goods regulatory requirements themselves.

Risk based regulation: Therapeutic goods are regulated by examining evidence of their risks and comparing that to the evidence associated with their benefits. The identified level of risk determines:

- the amount and type of information needed for review
- the degree of scrutiny necessary before the product can be made available in Australia and the level of safety monitoring once it is available.

The amount of regulatory oversight needed to appropriately manage risks depends on the nature and intended use of the product, and the level of risk ultimately determines the manner in which the public can gain access to that product. This risk-based approach to regulation allows greater effort to be directed to those therapeutic goods which pose greater risks to a patient's health.

Oversight of manufacturing: The *Therapeutic Goods Act 1989* also requires, with certain exceptions, that manufacturers of therapeutic goods hold a licence (for medicines and biologicals) or a conformity assessment certificate (for medical devices). Manufacturers of therapeutic goods are regularly inspected by TGA or comparable overseas regulators to ensure ongoing compliance with manufacturing requirements.

Post market monitoring: Once therapeutic goods receive approval for supply, they are subject to ongoing monitoring to evaluate safety and efficacy. This is critical as not all risks associated with a product can be identified prior to marketing approval. A key mechanism in this monitoring is adverse event reporting.

All health professionals are encouraged to report adverse events, which include

- serious or unexpected reactions to medicines and serious medicine interactions
- faults or problems with medical devices that have resulted, or could have resulted, in adverse events.

Importantly, an adverse event is not always caused by the therapeutic good itself. An adverse event could be a result of incorrect user interaction or other circumstances such as two properly functioning devices that do not operate as intended when used in combination. The line between therapeutic goods issues and clinical practice issues can also be difficult to assess prior to investigation of the adverse event.

Advertising: Advertising of therapeutic goods is regulated by the TGA. This is in addition to advertising restrictions under Ahpra requirements or other regulatory regimes (such as Australian Consumer Law). This has relevance for cosmetic surgeons advertising to the public. Not all therapeutic goods are allowed to be advertised to the public, and this may consequently restrict the advertising of cosmetic surgery services where these therapeutic goods are used. The regulation of advertising reflects the importance of consumers being properly informed so that they can select appropriate treatment options. Further information on advertising therapeutic goods to the public is available on the TGA website.

Compliance: The TGA monitors, and enforces where necessary, compliance with the legislation, regulations, and rules for therapeutic goods; import, manufacture, advertising, supply, and export. The TGA promotes high levels of voluntary compliance by effectively engaging with and educating the regulated community, and works with other government bodies, including health and law enforcement agencies, to share information about therapeutic goods. A range of compliance actions are available to the TGA, ranging from educational activities to criminal prosecutions. Where subject to the therapeutic goods regulatory framework these actions may be applied to health professionals in instances of non-compliance, which often relate to advertising requirements and importation of unapproved products.

Issues

Post market issues for cosmetic surgery products

Post market issues can occur for any therapeutic good, including those used in cosmetic surgery. Device sponsors report low numbers of adverse event reports to the medical device incident reporting & investigation scheme (IRIS) about implantable cosmetic devices (excluding breast implants). This is because many adverse events:

- do not meet the TGA adverse event reporting threshold, in that the event led to death or a serious injury (or a near adverse event, which might have led to death or serious injury)
- are subject to exemptions from reporting (noting the TGA has consulted on changes to reporting exemptions).

Nevertheless, there have been systemic post market issues for some cosmetic surgery products:

Breast implants: There have been a number of issues in respect of breast implants. These include issues for specific breast implant products (PIP implants, Cereform implants and Silimed implants) as well as broader issues such as breast implant associated anaplastic large cell lymphoma . A central hub for information on breast implants is available on the TGA website. The Australian Breast Device Register (ABDR) has been established to track the long-term safety and performance of breast implants as well as identify best surgical practice to help safeguard health outcomes for patients. Plastic, reconstructive, cosmetic, and general breast surgeons are strongly encouraged to contribute to the ABDR.

Cosmetic procedures: While outside the surgical scope of this Ahpra review, products associated with a range of cosmetic procedures, including cosmetic injections and dermal fillers, are a continuing focus for the TGA. Moreover, the TGA is monitoring the deceptive health claims and significant risks related to devices marketed for use in medical procedures for "vaginal rejuvenation" (www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-efforts-safeguard-womens-health-deceptive-health-claims). Some product manufacturers, sellers, and clinics have made claims about the procedures being able to treat conditions related to menopause, urinary incontinence, or sexual function, by use of lasers and energy-based devices on vaginal tissue.

Use of unapproved products

There are a number of ways that patients can gain access to products that have not been approved for use in Australia. In the context of cosmetic surgery, the special access scheme and authorised prescriber arrangements are particularly relevant.

These pathways allow certain health practitioners to access unapproved products for their patients or for use in their practice. In both these schemes the use of the unapproved product is a clinical decision for the health practitioner, who is best placed to determine the needs of the patient, and informed consent from the patient is of critical importance. The prescribing health practitioner also has primarily responsible for reporting adverse events or defects arising from the use of unapproved therapeutic goods accessed under these programs.

Off-label use of therapeutic goods

It should also be noted that medical devices may be used for purposes other than that intended by the manufacturer. Similarly, prescription medicines may be used 'off-label' for an indication or intended purpose other than those approved by the TGA, for example, when there are no suitable TGA-approved medicines available for the treatment of a certain condition. Such 'off-label' use is a clinical decision made at the discretion of the treating clinician who is responsible for obtaining informed consent from their patient and ensuring that the therapeutic good is the appropriate treatment option and carries a positive benefit–risk profile.

There may be circumstances where the sponsor becomes aware of the 'off-label' use of its therapeutic goods that are included in the ARTG and requests a Special Access Scheme (SAS) notification or approval to ensure legal supply of the product under the therapeutic goods legislation. The TGA administers the SAS to enable access to unapproved therapeutic goods for individual patients on a case-by-case basis. In life-threatening cases, the SAS Category A notification pathway is available to allow medical practitioners to supply an unapproved therapeutic good to a particular patient.

Potential adverse event mandatory reporting for health facilities

Between October and December 2021 the TGA consulted on a *Discussion paper on the potential for mandatory reporting of medical device adverse events by healthcare facilities in Australia*. Almost three quarters of respondents were in favour of introducing mandatory reporting of medical device related adverse events by healthcare facilities in Australia. Feedback to the consultation has been considered by government, noting that if mandatory reporting is to be introduced, work would need to be undertaken with healthcare facilities to facilitate accurate and timely reporting.

The TGA has been requested by the Australian Government to work closely with the Australian Commission on Safety and Quality in Health Care (ACSQHC), state and territory health departments, and private and day hospitals to progress how this initiative could be implemented using existing frameworks where possible. It should be noted that this proposal would include many facilities where cosmetic surgery is undertaken.

Patient information for implantable medical devices

From December 2021 implantable medical devices are required to have patient information materials available for provision to the patient in the form of both Patient Implant Cards (PICs) and Patient Information Leaflets (PILs). The requirements were introduced following a number of issues around a range of implantable devices that illustrated that patients often are not fully aware of the medical devices implanted into their bodies, have a poor understanding of the benefits and risks of these implants prior to agreeing to the procedure, and are often unaware of emerging issues for such devices as post market information comes to light over time. PICs are a static resource issued at the time of the procedure, while PILs are designed to be updated over time as evidence on issues for the device emerge (and available electronically from the manufacturer of the implant).

It should be noted that breast implant procedures were a key driver for patient information material reforms, given the range of breast implant related issues over the past decade (and which continue). Concerned patients contacting TGA are often unaware of which breast implant they received (brand and model details). Even if the issues are not relevant to their implant, the only option for TGA is to refer them to their surgeon (who may no longer be practicing). PICs aim to address this. Patients are also routinely unaware about the life span of breast implants, along with possible complications, or the various issues with these devices which emerge over time. PILs designed to address this.

These issues raise significant concerns about the effectiveness of informed consent discussions. Both PICs and PILs should be a useful resource for cosmetic surgeons to improve their clinical practice and to improve informed consent for their patients.

The therapeutic goods regulatory framework does not regulate clinical practice, so the provision of PICs at the time of the procedure, and of the PIL to the patient as part of the informed consent discussions, is not a statutory requirement for the surgeons (including cosmetic surgeons) implanting medical devices, or for the health care facilities where these procedures are performed. However, it is strongly encouraged as best practice.

Patients with cosmetic implants can also experience poor handover when their medical practitioner dies, ends the professional relationship, or closes or relocates their practice. Breast implants and other cosmetic implants are expected to last for many years, but cosmetic surgeons may not always facilitate the continuing care of their patients when they relocate or change the nature of their practice. For patients with implants, the Medical Board of Australia *Good medical practice: a code of conduct for doctors in Australia* requirements could be strengthened to ensure better continuity of care for the lifetime of their implant.

Regulation of devices without medical intended purpose

While the TGA does not routinely regulate cosmetic products, as discussed above there are a range of products regulated as therapeutic goods which are used in cosmetic surgery. In addition to cosmetic use, many of these products also have a medical purpose (such as reconstructive surgery).

In early 2018 TGA consulted on a range of issues around the scope of the medical device regulatory framework, and this included some proposals to regulate some products without a medical intended purpose. This included some product categories relevant to cosmetic surgery, including:

- Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
- Equipment intended to be used to reduce, remove, or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

Feedback to the consultation is being considered by government, and should these changes be implemented it will impact the regulatory oversight of these devices used in cosmetic surgery.

Emerging medical device technologies

Some medical devices are designed by the manufacturer to be adapted for patients and are regulated as for other medical devices. However medical devices which are constructed or modified for individual patients may be regulated by the TGA as either custom-made or personalised medical devices.

The new personalised medical devices framework has been put in place from February 2021 in response to rapid developments in recent years in advanced manufacturing and digital technologies. This has expanded the types of devices being produced in this way and increased the availability of the technology. This is not limited to personalised medical devices, and the TGA has also be examining other emerging technology issues, such as software that is a medical device in its own right (including apps) and cyber security of medical devices.

While requirements around emerging technologies are not specific to cosmetic surgery, practitioners should be aware of these requirements. The emergence of new technologies such as 3D printing has expanded the potential for products made for individual patients, and health practitioners in a variety of fields need to be aware these may bring additional regulatory responsibilities. In particular the production and use of custom or personalised medical devices are often beyond the scope of clinical practice oversight, and also may be outside the scope of the normal professional insurances associated with clinical practice.

Consultation questions

Code and Guidelines

1. Do the current *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures* adequately address issues relevant to the current and expected future practice of cosmetic surgery and contribute to safe practice that is within a practitioner's scope, qualifications, training and experience?

The guidelines cover a number of issues also relevant to therapeutic goods, including advertising requirements and informed consent (whether for unapproved therapeutic goods being used in cosmetic surgery procedures, or the provision of patient implant cards and promotion of patient information leaflets as part of informed consent discussions where implantable medical devices are being used).

While the issues detailed below are relevant across a range of surgical practice (not just cosmetic surgery), it may be appropriate to amend the *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures*:

- 4. Consent (in subsection 4.1) where implanted medical devices are being used in the procedure:
  - to include provision of patient implant cards (PICs) and patient information leaflets (PILs), as information which must be provided to patients to support informed consent and require specific discussion of the implants being used, possible alternatives, and the associated risks and benefits, including the expected lifespan of the device
  - to require disclosure of any off-label use of therapeutic goods or unapproved products (in line with the existing obligation for information on whether the procedure is new or experimental), noting that use of such products is a clinical decision made by the medical practitioner which should be clearly and explicitly communicated to the patient
- 5. Patient Management:
  - to include provision of the patient implant card (PICs) following the procedure, as part of post-procedure care (where implanted medical devices are being used in the procedure), and include information to the patient (and other relevant health practitioners involved in their ongoing care) on their implanted device, including recommending regular checks of the PIL on the manufacturer's website to alert them to any emerging issues with their implanted device
  - to require ongoing clinical oversight be arranged (including access to clinical records) where cosmetic surgeons cease practicing, to ensure support for patients for the lifetime of implanted medical devices (which will often span many years and in some cases will be as long as the patient's lifetime)
  - to strongly encourage adverse event reporting in relation to cosmetic surgery procedures
- 8. Training and experience:
  - to note that where medical devices are in use for a procedure, specific training for this equipment or in the use of implants will often be required
- 10. Advertising and marketing:
  - to expand on therapeutic goods advertising requirements. For example, this section currently refers practitioners to the Therapeutic Goods Advertising Code and TGA guidance on advertising cosmetic injections, and might also include reference to advice on other cosmetic procedures, including breast implants and patient information for implants.

2. What changes are necessary and why? What additional areas should the guidelines address to achieve the above purpose?

While it is beyond the scope of the TGA's regulatory framework to require health practitioners to pass on patient information materials (PICs and PILs) to individual patients, it is the clear intent that these materials be given to patients. They should also be useful tools for cosmetic surgeons, supporting effective informed consent conversations (PILs), and providing key information which patients can refer to in the event of future issues with implants.

It is also clear that in practice informed consent processes are not effective in educating patients on issues for implanted medical devices. No medical device should be implanted without the patient being fully aware of the implications for their ongoing care (including device replacement), and provision for ongoing care of patients for the lifespan of that implanted medical device.

The TGA is happy to work with Ahpra on updating the Guidelines, as well as related information on the Ahpra website, such as for consumers. This may include cross referral to TGA resources for consumers on cosmetic procedures, and patient information on implantable medical devices, including those used in cosmetic surgery.

3. Please provide any further comment in relation to the use of codes and guidelines relevant to the practice of cosmetic surgery

While recognising the distinction between the regulation of clinical practice by Ahpra, and the regulation of therapeutic goods by the TGA, these areas of intersection might be useful areas for cooperation.

Management of notifications

4. Having regard to Ahpra and the Medical Board's powers and remit, what changes do you consider are necessary to the approach of Ahpra and the Medical Board in managing cosmetic surgery notifications, including their risk assessment process, and why?

Where a notification is made about an event relating to the performance of a cosmetic surgeon, it may be unclear whether there are associated issues around any therapeutic goods used in the event. Reporting of such events under TGA's adverse event reporting framework may also be appropriate. Joint investigation may also be required where it is initially unclear whether issues relate to surgeon or therapeutic good performance (or both).

5. Please provide any further relevant comment in relation to the management of notifications about medical practitioners involved in cosmetic surgery.

Note that it may become compulsory for health facilities to report medical device adverse events in future.

Advertising restrictions

6. Is Ahpra and the Medical Board's current approach to regulating advertising in cosmetic surgery sufficient?

As outlined above, TGA's advertising requirements may also be relevant for cosmetic surgeons using, and particularly promoting their use of, therapeutic goods. As noted in the *Guidelines for registered medical practitioners who perform cosmetic medical and surgical procedures* and the *Guidelines for advertising a regulated health service*, compliance with all applicable regulatory requirements is necessary (also including other frameworks, such as the Australian Consumer Law).

7. What should be improved and why and how?

While the requirement to also comply with the therapeutic goods advertising requirements is noted, these details might usefully be expanded to illustrate the need for active consideration of therapeutic goods advertising requirements by cosmetic surgeons (and indeed all medical practitioners).

8. Do the current Guidelines for advertising a regulated health service adequately address risks in relation to advertising of cosmetic surgery, or is a more specific regulatory response required?

Section 2.2 of the *Guidelines for advertising a regulated health service* outlines that advertising a health service must also comply with therapeutic goods advertising requirements. Further details are included in appendix 3 of those Guidelines, which refers readers to the TGA website and notes key regulatory instruments such as the *Therapeutic Goods Act 1989* and relevant regulations.

TGA has recently undertaken significant advertising reforms, including a new Therapeutic Goods Advertising Code (which came into effect from 1 January 2022, with a transitional period to 30 June 2022). The TGA can assist with content describing the difference between advertising of a service versus a product (that would trigger the therapeutic goods advertising requirements). The list of relevant regulatory instruments also omits the *Therapeutic Goods (Medical Devices) Regulations 2002*.

9. Does the promotion of cosmetic surgery via social media raise any issues that are not adequately addressed by the advertising guidelines, or that require any specific regulatory response?

The TGA website includes specific guidance on social media advertising (soon to be updated to reflect the new Therapeutic Goods Advertising Code). It may be appropriate to expand this information in the Guidelines for advertising a regulated health service.

10. Please provide any further relevant comment in relation to the regulation of advertising.

The TGA is happy to work with Ahpra on updating the Guidelines on both advertising and cosmetic medical and surgical procedures, which may also benefit from expansion of this information to prompt readers to seek further information on therapeutic goods advertising requirements.

Title protection and endorsement for approved areas of practice

11. To what extent would establishing an endorsement in relation to the practice of cosmetic surgery address relevant issues of concern in the sector (including patient safety issues)?

While clinical practice is beyond the scope of the TGA's regulatory framework, we note that the safety and performance of surgical tools, implants, and medicines used in cosmetic surgery rely heavily on the skills, training, and experience of the health practitioners involved in that surgery. This includes patient selection and management processes, the surgical procedures, surgical support processes, and in post-surgery follow-up.

The TGA's recent experiences in addressing serious patient safety problems involving surgical implants, such as breast implants and surgical meshes, have highlighted the interplay between the safety, quality, and performance of the implant with the skills and competency of the health practitioners involved in the surgery and patient management. Adverse event rates for the same product often vary depending on variation in surgical technique, patient selection, and the skill of the surgeon.

[redacted], the medicine procurement, storage, and handling practices of some cosmetic surgery health services also appears to be sub-standard and unsafe for patients. The apparent failure to observe these basic safety and quality protocols suggests that the professional skills and training of the health practitioners involved in those services may have also failed. The quality, safety and efficacy of therapeutic goods depends on the health practitioners involved in administering or using those goods in line with the manufacturer's instructions and with the relevant regulatory and safety protocols.

The TGA does not offer a view about title protections or endorsements. However, there is clearly a need for a strong policy response to improve the training, skills, competency, and professionalism of health practitioners involved in cosmetic surgery. That policy response should include an explicit component to improve compliance with basic safety, quality, and regulatory protocols that support the safe use of therapeutic goods.

12. Would establishing an endorsement in relation to cosmetic surgery provide more clarity about the specific skills and qualifications of practitioners holding the endorsement?

As previously stated, the TGA does not offer a view about title protections or endorsements. However, there is clearly a need for a strong policy response to improve the professionalism of health practitioners involved in cosmetic surgery.

13. What programs of study (existing or new) would provide appropriate qualifications?

The training, skills, competency, and professionalism of health practitioners involved in cosmetic surgery need strengthening. The policy response should include an explicit component to improve compliance with basic safety, quality, and regulatory protocols that support the safe use of therapeutic goods.

14. Please provide any further relevant comment in relation to specialist title protection and endorsement for approved areas of practice relevant to cosmetic surgery.

The TGA is happy to work with Ahpra and the MBA on policy responses to improve compliance with basic safety, quality, and regulatory protocols that support the safe use of therapeutic goods in cosmetic surgery.

Cooperation with other regulators

15. Are there barriers to effective information flow and referral of matters between Ahpra and the Medical Board and other regulators?

Issues around clinical practice may be identified through the TGA's post market and compliance activities, and this is conveyed to Ahpra on an ad hoc basis where issues are identified. Reciprocal advice of therapeutic goods issues identified in the context of Ahpra investigations is also helpful. Similarly exchange on advertising issues also takes place on an ad hoc basis.

In 2017-18 systemic issues around cosmetic procedures with dermal fillers were identified in NSW, (including a parliamentary inquiry). The TGA worked cooperatively with NSW Health and the NSW Health Care Complaints Commission to address issues at the intersection between therapeutic goods regulation and cosmetic practice. While procedures with injectables are out of scope for this review, this example illustrates a model for cooperation where systemic issues arise in a sector.

16. If yes, what are the barriers, and what could be improved?

The joint investigation outlined above provides a model for joint investigation of issues where these arise. The TGA would welcome engagement with Ahpra should issues requiring investigation also involve therapeutic goods elements (including but not limited to cosmetic surgery).

To date the need for information sharing beyond existing ad hoc arrangements has not been identified as an issue for the TGA, but if more systemic information sharing has been identified by Ahpra as potentially helpful, options can be explored.

17. Do roles and responsibilities require clarification?

While the delineation between issues relating to clinical practice and therapeutic goods are generally clear, in practice the investigations of therapeutic goods issues may also highlight potential clinical practice issues.

18. Please provide any further relevant comment about cooperating with other regulators.

The TGA would welcome the opportunity work with Ahpra on joint investigations and is happy to explore more systemic information sharing.

Facilitating mandatory and voluntary notifications

19. Do the Medical Board's current mandatory notifications guidelines adequately explain the mandatory reporting obligations?

While a separate reporting framework to that for Ahpra, there are also reporting obligations in the TGA regulatory framework. We note potential changes for mandatory reporting for health facilities on adverse events notifications for medical devices (as outlined in the *Issues* section above), which will include many cosmetic surgery procedures.

20. Are there things that prevent health practitioners from making notifications? If so, what?

While Medical Board notifications are beyond the TGA regulatory remit, any opportunities arising from facilitating such notifications which may also provide avenues for adverse event notifications to the TGA would be of great interest.

21. What could be improved to enhance the reporting of safety concerns in the cosmetic surgery sector?

As outlined above, sharing of reporting between the TGA and Ahpra where relevant issues are identified is helpful.

22. Please provide any further relevant comment about facilitating notifications

The TGA would welcome the opportunity to coordinate with Ahpra on facilitating therapeutic goods adverse event notifications by medical practitioners (including but not limited to cosmetic surgeons).

Information to consumers

23. Do the Medical Board's current codes and guidelines adequately describe the obligations of practitioners who **perform cosmetic surgery to provide sufficient information to consumers and obtain informed consent?**

It is apparent from interactions with cosmetic surgery patients that many do not fully understand the risks and benefits associated with cosmetic surgery. For example, in the context of breast implant issues, many patients are not aware of the limited lifespan of breast implants and the need for them to be replaced after approximately 10 to 15 years. Such issues need to be communicated effectively as part of informed consent discussions. This has prompted TGA to develop a series of patient fact sheets (noted below). This is not unique to cosmetic procedures, and is of concern for many implanted medical devices.

Note the TGA provides guidance which can support cosmetic surgeons in educating consumers and ensuring informed consent:

- PICs and PILS - www.tga.gov.au/community-qa/patient-implant-cards-and-information-leaflets
- Consumer Medicine Information – www.tga.gov.au/consumer-medicines-information-cmi

- Series of patient fact sheets for some cosmetic procedures:
  - Breast implants - www.tga.gov.au/breast-implants-things-consider-having-procedure
  - Dermal fillers - www.tga.gov.au/community-qa/things-consider-undergoing-procedures-involving-dermal-fillers
  - Micro needling- www.tga.gov.au/community-qa/microneedling-things-consider
  - Cosmetic injections - www.tga.gov.au/cosmetic-injections

24. If not, what improvements could be made?

Opportunities to facilitate use of and dissemination by cosmetic surgeons of the information for consumers detailed above would be welcome. As outlined, informed consent practices need to be improved for implanted medical devices, and these patient information materials should be a useful resource.

25. Should codes or guidelines include a requirement for practitioners to explain to patients how to make a complaint if dissatisfied?

Yes, all patients should be provided with information regarding where and how to make a compliant, and/or report any adverse events or near miss adverse events. Patient information materials and implant cards are required to have details for how to contact the TGA if the event involves an implant or medical device.

26. In the context of cosmetic surgery, does the Ahpra website and public register of practitioners provide sufficient information about medical practitioners to inform consumer choices?

As outlined above, ongoing clinical oversight is required for the lifetime of a patient's implanted medical device. This can prove difficult for patients with implants when their surgeon relocates or ceases practice. Ahpra's public register of practitioners could potentially be enhanced to allow patients to identify a doctor suitable for their needs or to whom their records have been transferred.

Greater referral on the Ahpra website to the TGA's information for consumers (particularly consumer advice on things to consider before having breast implants (www.tga.gov.au/breast-implants-things-consider-having-procedure) would be welcome. TGA would also be happy to work with Ahpra on developing further resources.

27. If not, what more could/should Ahpra and the Medical Board do to inform consumer choices?

A number of the consumer focus information tools the TGA has developed in recent years have been in reaction (at least in part) to cosmetic surgery issues.

For example, in the context of various issues in breast implant surgery, consumer inquiries indicate many are not aware of the which devices have been implanted. The brand or specific product may be relevant when issues with implants arise, and if this is not known by the patient, they need to refer to their surgeon to find out whether they are affected. In practical terms this can be difficult (eg if the surgeon has ceased practicing). The patient implant card (PIC) has been implemented for implantable medical devices (including cosmetic medical devices) to address this. Promotion of passing the PIC to patients of any implant surgery is strongly recommended.

It is also clear from consumer inquiries to the TGA that many recipients of implants (particularly but not limited to breast implants) are not aware that implanted medical devices often have a finite lifespan (for example breast implants need to be replaced after 10 to 15 years). This is critical information in the context of informed consent by the patient, and while it may be communicated by cosmetic surgeons, that communication has clearly not been effective where patients have no ongoing awareness of this issue. Requirements around informed consent should strongly encourage ensuring the lifespan of any implanted medical devices is understood by patients, and patient information leaflets (PILs) can assist in this conversation.

Participation in device and procedure registries is also a key way to track patient health outcomes. In the context of breast device surgeries, participation in the Australian Breast Device Registry (ABDR) is also encouraged (both for surgeons, and their individual patients). We note that in tracking health outcomes, the ABDR monitors both the long-term safety and performance of breast devices and benchmarks the quality of surgery involving breast implants, breast tissue expanders and acellular dermal matrices, so is relevant for both therapeutic goods and clinical practice.

28. Is the notification and complaints process understood by consumers?

Promotion of adverse event reporting and participation in the ABDR by consumers/patients is strongly encouraged, and any opportunity to cross promote this in the content of Ahpra and the practice of cosmetic surgery is welcomed.

29. If not, what more could/should Ahpra and the Medical Board do to improve consumer understanding?

As outlined above, greater emphasis of implanted devices, including in the context of informed consent but also broader education or promotional activities, would be of assistance. This includes use of existing resources, such as PICs, PILs and participation in registries.

30. Please provide any further relevant comment about the provision of information to consumers.

Greater referral on the Ahpra website to the TGA's information for consumers (such as those detailed above) would be welcome.

Further comment or suggestions

31. If you have any further comment relevant to Ahpra's and the Medical Board's regulation of cosmetic surgery including and/or suggestions for enhancements not mentioned in response to the above questions, please provide it here

As outlined above, there are many points of interaction between the regulatory roles of Ahpra and the TGA. Some of these are specific to cosmetic surgery, while others may also have broader application (such as for surgeons more generally, or for all or many health practitioners). TGA welcomes opportunities to work cooperatively with Aphra, on specific issues such as investigations and compliance matters, or on broader issues such as mutual input to professional guidance and consumer education.