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Submission to the Medical Board on Guidelines for registered medical practitioners who provide cosmetic medical or surgical procedures

. The guidelines propose:

- *a seven-day cooling off period for all adults before procedures*
- *a three-month cooling off period before procedures for all under 18s, along with mandatory assessment by a registered psychologist or psychiatrist*
- *explicit guidance on informed patient consent, including clear information about risks and possible complications*
- *explicit responsibility for post-operative care by the treating practitioner, including emergency facilities when sedation or analgesia is involved*
- *mandatory face-to-face consultations before prescribing schedule 4 (prescription only) cosmetic injectables*
- *detailed written information about costs, and*
- *limits on where cosmetic procedures can be performed, to manage risk to patients."*

As a non-surgical cosmetic doctor with 20 years experience in the field, I would like to add my comments to the public consultation. My comments relate predominantly to non-surgical interventions. I applaud the Medical Board on this initiative, but am sceptical that it will ultimately produce a set of legislated guidelines, in view of the failure of previous attempts. However I remain eternally optimistic that this wonderful area of practice can be regulated to a point where we can be proud to provide safe, consistent, world-class quality care
The cosmetic surgery arena is a whole separate field of discussion, with greater risks and complications, which needs major changes in the way it is regulated. At least it is an area where the major providers are registered medical practitioners, unlike the non-surgical arena, where providers can be doctors, dentists, registered nurses, enrolled nurses and non-medical aestheticians/laser therapists. Whilst I agree with the nature and extent of the problem for consumers who seek cosmetic medical and surgical procedures from register medical practitioners, as outlined in the consultation paper, the problem is far wider with the inclusion of other healthcare providers operating outside their regulated scope of practice. At the very least the Nursing and Midwifery Board need to embrace a stricter set of guidelines.
However, all the guidelines and regulations in the world will be meaningless if AHPRA fail to adequately ensure that the guidelines are actually followed. AHPRA needs to provide a simpler and less intimidating means of notification of possible breaches, which is neither punitive nor accusatory, which provides confidentiality to the notifier. Many of the breaches are already in the public arena, such as print advertising, and social media, so reporting breaches should be seen as assisting AHPRA, not a 'personal vendetta' or witch hunt.
Specific issues in the proposed guidelines are discussed below, including excerpts from the Public Consultation document.

<u>FACE to FACE CONSULTATIONS SHOULD BE MANDATORY</u> - as doctors we are expected to perform our duties according to the Good Medical Practice code of conduct. In everyday medical practice we are all aware that prescribing S4 drugs requires a face to face consultation prior to that specific prescription, except maybe in the instance of repeat prescription where the patient is well-known to the Dr, who has comprehensive medical records eg OCP repeats, cholesterol-lowering drugs, antihypertensives, etc. It is generally not acceptable practice to have a consultation with a new patient via phone or Skype, in the presence of a registered nurse (as distinct from a Nurse Practioner), provide the prescription and then delegate the administration, unless the patient has significant medical need with limited access to services. It is even more reprehensible to have a doctor who is paid to retrospectively sign off on apparent 'standing orders', documented only by a registered nurse, where the patient is never seen by that doctor. This seems to be very mainstream protocol in many clinics in Australia, and there appears to be some confusion generated by the regulatory authority as to what constitutes acceptable practice (in particular with 'standing orders'). In

the cosmetic medical arena there can be absolutely no medical need for good medical practice to deviate from the norm to this extent - it is purely driven by financial gain.

"The Australian Health Ministers' Advisory Council's (AHMAC) Inter-jurisdictional Cosmetic Surgery Working Group was tasked with undertaking the review. In its report, Cosmetic Medical and Surgical Procedures – A National Framework, the group expressed concerns about the inconsistent nature of regulation in an area of practice with 'rapidly changing technology' and 'burgeoning activity'. The group noted that these medical and surgical procedures 'are not a commodity to be treated lightly – they are medical interventions which carry risks and a complication and failure rate'.16

The AHMAC Working Group also made recommendations to other national bodies that were within the scope of their work including that:

- *the Nursing and Midwifery Board of Australia consider the need for supplementary guidelines to its code of conduct for registered nurses.18*

- *the Australian Radiation Protection and Nuclear Safety Agency's (ARPANSA) Radiation Health Committee undertake work to address gaps in the current regulation of lasers and IPLs which are used by both registered health practitioners and unregulated providers.*

16 Australian Health Ministers' Conference, *Cosmetic Medical and Surgical Procedures – A National Framework,* 2011, http://www0.health.nsw.gov.au/pubs/2012/cosmetic_surgery.html "

18 The Nursing and Midwifery Board of Australia is currently considering options in relation to regulation of nurses who provide cosmetic procedures and is aware of, and has the opportunity to contribute to this public round of consultation.

19 The ARPANSA Radiation Health Committee is currently considering options for nationally consistent regulation of these devices.

21 Department of Health, *Review of the Regulation of Cosmetic Interventions - Final Report*, UK, 2013, https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions

22 ibid.

23 General Medical Council, Statement, *GMC responds to RCS cosmetic surgery proposals*, 23 January 2015, http://www.gmc-uk.org/news/26090.asp

24 Independent Healthcare Advisory Services, *Good Medical Practice in Cosmetic Surgery,* UK, 2013, http://www.independenthealthcare.org.uk/cat_view/126-cosmetic-ihas/127-cosmetic-ihas/menu-id-864

25 General Medical Council, *Good practice in prescribing and managing medicines and devices*, UK , 2013, http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp

26 Adams J & Thorn M, 'Doctors and interventions with well people', Chapter 25 in St George IM (ed.), *Cole's medical practice in New Zealand*, 12th edn, Medical Council of New Zealand, Wellington, 2013.

27 Medical Council of New Zealand, *Statement on cosmetic procedures*, NZ, 2011, http://www.mcnz.org.nz/support-for-doctors/resources/

28 Scott K, 'Under the knife: an analysis of the Medical Council of New Zealand's Statement on Cosmetic Procedures', *Journal of Law and Medicine*, 16(4), 2009, pp 625-52

29 The MCNZ's statement was revised in 2011 to add guidance for doctors who perform tumescent liposuction.

The Medical Council of New Zealand (MCNZ) has noted the ethical, resource and regulatory issues that arise when medical practitioners provide cosmetic procedures that are undertaken where there is no 'medical condition'. The MCNZ makes its expectations clear; ***a medical practitioner's usual professional obligations apply regardless of the nature or setting of the practice.26*** *The MCNZ's Statement on cosmetic procedures outlines the standards expected of medical practitioners who perform cosmetic procedures in New Zealand.27 The statement was prompted by concern that the previous regulatory framework was inadequate in protecting consumers having cosmetic procedures provided by medical practitioners.28*

The statement includes expected training, skill and expertise, advertising, patient assessment and informed consent including a mandatory cooling off period for patients considering a 'category one' (major) cosmetic surgical procedure.[29] *Public*

RISK MANAGEMENT - WHERE COSMETIC PROCEDURES ARE PERFORMED it is quite common for these non-invasive cosmetic procedures to be performed in Beauty Therapy Salons, MediSpas, Hair Salons, Tanning Salons, gyms, homes etc in addition to medical rooms . Most of these premises are non-medical establishments and the owners are paid a service fee for the cosmetic injector/operator (often an RN) to perform treatments on their premises. There are often no provisions for Infection-control, hygiene and sterility, limited emergency resuscitation equipment and obviously no emergency drugs ((RNs are not licensed to transport, prescribe and administer many of the emergency drugs) Neither is there a medical practitioner on site. It is common practice for RNs who own their own businesses to pay a doctor to act as their prescribing doctor - both for the purchase of the S4 drugs and to authorise the 'standing order' by Skype. For a doctor, who may own their own practice, to provide such a service for a fee, is unethical and a breach of good practice guidelines. In effect, they are on selling the S4 drugs to the nurse who takes on the financial responsibility to the drug company. The right to prescribe carries with it the responsibility for the health and well-being of the patient. Many of these 'prescribing doctors' never see the patients they are prescribing these drugs to - how can that be good practice?

RESPONSIBILITY OF THE PHARMACEUTICAL COMPANIES - The pharmaceutical companies have one overriding objective - to make sales! They do provide a lot of training to doctors and nurses, but they also seem to 'court' the more prolific injecting nurses as they tend to generate a lot of sales. The reps are in a very unique position, having intimate access to many clinics, and a knowledge of the levels of supervision provided. On numerous occasions I have felt compelled to advise a rep that a particular injector is not registered with AHPRA, or is only an EN, or not adequately insured, or has dubious level of supervision. The usual response is "it is not our job to police". However, I believe they often turn a blind eye to many breaches simply because it would impact on sales. It must become mandatory that the injectors produce current copies of their AHPRA registration and their insurance level in order to perform any company sponsored workshops or training, and the doctors should also produce theirs whenever they order product. Also the reps/BDMs who are non-medical must only train nurses in the presence of a doctor. If an adverse event were to occur with only the training nurse and non-medical company rep/trainer, who would be responsible for the patient? I believe the pharmaceutical companies should be strictly regulated with regards to their behaviour as this is a far more serious issue than which doctor received free sandwiches from the drug rep!

COOLING OFF PERIODS With non-surgical cosmetic procedures, it would be wise to have a cooling off period, or maybe a 'no treatment on the day of first consult' rule. Patients are fairly mobile and will often seek out different providers for botulinum toxin and filler treatments. It is incumbent on every practitioner to have a full consultation and examination, including informed consent, prior to treatment. Thus, even if they have had treatments elsewhere, it is important to ascertain what these were and why they have come. Many of these will have a body dysmorphic disorder, or are chronically unsatisfied with their appearance. If we rush in to treat with minimal history beyond ' I've had Botox before and I want more now", then we may be doing them a great disservice. Hence a limited cooling-off would be wise. With surgical or non-surgical treatments in the under-18s, I believe it should be a requirement to get a prior referral from a GP, psychologist or psychiatrist. That negates the need for the cosmetic practitioner to be forced to refer patients prior to treatment. But that does seem a little incongruous given that the same person can go get a permanent tattoo without too much opposition or regulation. But... tattoos are not medical procedures - these are.

"Medical assessment of a consumer's motivation for the procedure is a critical step as there is evidence to suggest that some people seeking cosmetic procedures have a distorted body image (including conditions such as Body Dysmorphic Disorder) which may make them an unsuitable candidate for cosmetic procedures."[43]

"A key element of consent is ensuring that the consumer has 'time to reflect, before and after they make a decision, especially if the information is complex or (it) involves significant risks.'[57] *A two stage consent process, where the patient has a 'cooling off period' after their initial consultation with the medical practitioner, encourages a period of reflection during which the patient 'has the opportunity to consider the full implications' of the proposed procedure."*

INFORMED CONSENT

"Consumers making rushed decisions to have cosmetic medical and surgical procedures provided by medical practitioners, without adequate information

Health care is characterised by encounters in which the consumer knows less about services and procedures than the provider. This information asymmetry can create a power imbalance which places the consumer at a disadvantage."

Cosmetic procedures are all results-driven elective procedures. It is important for the consumer to be educated and fully informed about all aspects including

1. the relevant experience and qualifications of the practitioner performing the procedure
2. the nature and the relative risks and costs of the procedure
3. where the procedure will be performed
4. specific information regarding access to aftercare in the event of a problem
5. written info on all of the above, with links to further information

QUALIFICATIONS AND TRAINING OF PROVIDERS

"Medical practitioners who perform cosmetic medical and surgical procedures have widely varying levels of qualifications, training and expertise. Cosmetic surgery is not a recognised medical specialty. Rather it is a field of practice that any registered medical practitioner may practise in. There is no minimum qualification or training required to provide cosmetic procedures. Any medical practitioner with a basic medical degree can perform cosmetic medical and surgical procedures in their own clinic (although the Board's code of conduct, Good medical practice, states that medical practitioners must recognise and work within the limits of their competence).[81] Consumers may find it difficult to distinguish between medical practitioners' qualifications. In the HQCC's report complaints about professional conduct included misrepresentation of qualifications and competence issues."[82]

This is a very important facet of the provision of cosmetic medical and surgical services. As doctors we must recognise and work within our existing skill level. Just because we have a medical degree does not give us competence in all areas of medical practice. In addition, there is certainly widespread confusion among consumers as to who is appropriately qualified to be performing these treatments. Many would not understand the difference between a **cosmetic surgeon** and a **plastic surgeon.** I believe there needs to be minimum standards in all areas of cosmetic intervention, with attainment of specific training goals through accredited training organisations, and the public needs to be made aware of the qualifications to look for. It might even be a consideration for cosmetic doctors to be accredited as 'cosmetic' only if they have attained a certain level of training eg Fellowship or Diploma of cosmetic medicine. Advertising one's 'membership' of a particular society or organisation does not imply any particular skill or qualification and may even be misleading.

The other providers of these services ie nurses, dentists, ENs, aestheticians, laser therapists and other non-medical practitioners, should also have to abide by some minimum standards of practice/advertising when performing treatments such as cosmetic injectables, laser for hair removal, vascular and pigmented lesions, skin needling, mesotherapy/lipodissolve, skin peels, PRP treatments etc. Many of these treatments are quite invasive with significant risks of complications (not the least of which is infection) and without medical supervision (eg to prescribe an appropriate antibiotic) the consumer is at risk of an adverse outcome which could have been avoided. These providers often advertise themselves as **'cosmetic specialists', 'cosmetic nurse specialist'**, or similar, falsely implying they have a specific and recognised qualification. If they are working independently, the public are at a disadvantage if it is then assumed they have adequate medical supervision (which they often do not).

Many doctors employ nurses to perform injectables and laser treatments in their practices without acquiring the necessary training to be fully competent in those procedures. This way of supplementing their own revenues by delegation is not ethical if the doctor's own scope of practice does not reflect similar skills, thus allowing for appropriate supervision of all aspects of the services provided.

The whole concept of 'teamwork' seems to have been lost in this field of medical practice as the competition for the readily available consumer dollar becomes ever more fierce. In all areas of healthcare there is usually a highly structured team of healthcare professionals who support each

other, but in cosmetic medicine the intensely competitive, ego-driven commercial nature of the business has eroded those standards. Many RN nurse injectors/cosmetic nurses are exceptionally skilled, but it is outside their scope of practice (and probably invalidates their medico-legal insurance) to purchase, transport, prescribe and administer S4 medications.

ACCESS TO RELIABLE INFORMATON AND ADVERTISING

The Australian public needs better access to cosmetic information online.
The TGA needs to differentiate between information and “advertising” online. In Australia, there is no room to provide adequate information to readers online, it is all considered “advertising”, when it is not, even in issues of patient safety.
Examples are that in Australia we can’t compare safety or effectiveness etc of different dermal fillers/toxins online because we can’t name them. We also can’t discuss journal articles with new and important information about fillers or toxins because we can’t name the drugs. This needs to change. Why should the public have to look at overseas websites to learn about products and procedures that they are having in Australia. Australia should become world-class in providing online cosmetic medical information to patients, instead of the situation now, which is unfortunately the reverse. The relevant Colleges of Cosmetic Medicine, Cosmetic Surgery or Plastic Surgery are all in a position to assist with this information.
However in the pursuit of providing appropriate, unbiased and relevant information to consumers we must also be careful to avoid advertising which offers inducements such as 'specials', 'packages' and 'finance arrangements', all of which could encourage consumers to hastily commit to procedures without fully considering all the risks and benefits.

LASER SAFETY AND USE

As lasers and IPLs become more widespread in the cosmetic industry, regulations covering their use need to become more specific and more stringent. Many companies selling lasers, which are very expensive items, offer training as a means of expanding their potential market. Thus the Class 3B and class 4 lasers, which used to only be sold to medical practitioners, are now in the hands of nurses and paramedical operators. The hazard here, is that all businesses have staff turnover, and if the original company-trained operator leaves or teaches another, it is quite possible to practice and perpetuate potentially hazardous techniques which may cause injury. There are no minimum standards in most Australian states. Lasers are categorised according to their potential to cause damage, particularly to eyes. There must be minimum standards set for those who own and operate these devices. It is especially important that the doctor supervising the use of a particular laser/IPL be fully competent in the use and potential complications of that device and not just delegate all responsibility to a nurse or therapist.