Submission No 1

COSMETIC HEALTH SERVICE COMPLAINTS IN NEW SOUTH WALES

Name: Dr Michael Molton

Date Received: 23 March 2018

1. Executive Summary

This author offers a cost effective, single solution to the four subjects contained within the call for submissions on cosmetic medicine in New South Wales.

This author's proposal is to

1)provide a window period of 2 years for all facilities who presently offer cosmetic medical procedures, to attain compulsory Accreditation with a healthcare standards accreditation provider.

2)in the meantime, to establish a 2 year moratorium on the creation or provision of new service outlets intending to provide cosmetic services (similar to that historically created in WA regarding over-supply of new pharmacies).

1.1 Accreditation

The issue of accreditation of facilities that offer cosmetic medical services was examined as far back by AHMAC in 2011, however this has never been implemented:

Australian Health Ministers' Conference 2011
AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL

COSMETIC MEDICAL AND SURGICAL PROCEDURES
A NATIONAL FRAMEWORK
FINAL REPORT
INTER-JURISDICTIONAL COSMETIC SURGERY WORKING GROUP
CLINICAL, TECHNICAL AND ETHICAL PRINCIPAL COMMITTEE

"there are notable gaps in accreditation of health services in Australia. A substantial and increasing number of procedures are performed in medical rooms. There is limited accreditation of services provided in medical rooms, dentistry and a range of allied health services provided in private practice.

As indicated previously, the new national model of safety and quality accreditation for health care organisations, including a set of national safety and quality health service standards, is intended to address these gaps and options for mandating the standards in relation to high risk areas are being examined"

1.2 The Accreditation Process

Accreditation bodies such as the *Australian Council on Healthcare Standards* require the owners/managers and staff of accredited practices to establish, follow, monitor and audit procedures, their complication rates, infection control, in fact all policies and protocols regarding all aspects of patient care and these must meet relevant *Australian Standards* and these methods of practice are recognised by the medical profession as the minimum standard of patient care.

Accredited healthcare facilities are audited (surveyed) on a regular basis by the accreditation supervisors.

Presently, accreditation of facilities that provide any form of healthcare is mainly voluntary. Acquiring accreditation of a healthcare facility is funded by the private owners of those practices and therefore offers little or no cost to the public.

1.3 How will compulsory accreditation address the four topics?

Topic 1 : Advertising using words like "Medi" or "Medical" by establishments which clearly are not medical;

How would compulsory accreditation solve this problem?

Accreditation of facilities that provide cosmetic medical procedures would be required to comply with advertising guidelines as set down by the profession to maintain accreditation status.

At present there are opportunistic entrepreneurs who appear to knowingly breach advertising guidelines and breach other codes of conduct set down by AHPRA and the TGA. In particular, it is unlawful to advertise scheduled medicines by name such as ‘Botox’, Dysport’, Juvederm’ etc. Ironically it is these opportunistic entrepreneurial operators who gain favour from the public searching online for a reliable and trustworthy source, because websites of reputable and experienced doctors follow the law and do not advertise these prohibited terms and therefore do not get found. Terms and phrases the public use on Google to search places that perform comsetic medical procedures such as Botox, Hyaluronic Acid, Medi-spa, are not contained in websites of doctors who follow the TGA/AHPRA guidelines.

Accreditation requires that all aspects of patient care are considered, including the requirement not to mislead patients, and in particular, only to advertise lawfully. Potential loss of accreditation due to failure to follow such codes of conduct would be a sufficient deterrent of unlawful and/or misleading advertising.

It follows therefore that whatever ‘title’ the facility be named, accreditation requires that recognised industry codes of conduct are followed, including advertising codes of conduct.

Accreditation also means personnel must demonstrate competence, experience and qualification. This is called ‘credentialing’ and requires demonstration of training, competence and experience within a defined scope of practice (SoP). So again, whatever a facility be named, the facility would be required to demonstrate currency of accreditation. Accreditation cannot be acquired or maintained if the personnel performing the procedures have not been formally credentialed to perform procedures within their SoP.

Presently there is no requirement of credentialing of the personnel who use these products and devices outside of accredited facilities, such as in medi-spas’. And in any case, holding a medical, surgical or nursing degree is insufficient to demonstrate the special skill sets involved with treatments in cosmetic medicine.

The products and devices used for the purpose of cosmetic medicine are categorised as prescription-only medications (injectables) or are TGA approved devices (for example lasers, ultrasound, radiofrequency devices). The use of these products and devices have potential complications, some serious. While regulatory frameworks exist in every state and territory these regulatory frameworks refer only to authorised users such as ‘medical practitioner’ or ‘nurse’ and ‘nurse practitioner’. The legislative instruments do not require specific credentialing of personnel since policing of such regulations would be problematic.

So, regardless of what a facility might be called, the benefits of accreditation require that industry codes of conduct, including advertising and the requirements to comply with credentialing within a defined SoP would provide a high degree of confidence that a minimum standard of patient care was uniform within the profession.

Topic 2. Use of tele-consulting where the doctor is not actually responsible for supervision and may have no competency in the area of cosmetic medicine;

2.1 How will compulsory accreditation remove the risks and complications of remote prescribing (telemedicine) in cosmetic medical procedures)?

There is overwhelming opposition within the medical profession to the practice of remote prescribing (telemedicine) in cosmetic medicine. Compulsory accreditation would require policies and protocols that are consistent with Codes of Conduct common to the vast majority of health profession bodies, and in this case telemedicine in cosmetic medicine would cease.

2.2 Evidence the vast majority of the medical professional bodies reject telemedicine in cosmetic medical procedures:

2.2.1 In 2015 AHPRA called for public submissions on new guidelines for cosmetic procedures. AHPRA provided four options for the basis of the new guidelines. Over 600 submissions were received and are viewable on AHPRA's website for your confirmation. The medical profession overwhelming recommended Option 3, which included the necessity to conduct a physical/mental evaluation, face-to-face, in-person with the medical practitioner responsible for the prescription of scheduled medications used for cosmetic medical purposes. The professional bodies that supported Option 3 in its entirety included, but was not confined to, the Royal Australian College of Surgeons, Australian Society of Plastic Surgeons, Royal Australian College of General Practitioners, the Cosmetic Physicians Society of Australasia, the Australian College of Aesthetic Medicine, Royal Australian College of Physicians and many individual medical practitioners.

2.2.2 The British General Medical Council banned all remote prescribing in cosmetic medicine in June 2016 stating this practice had no place in cosmetic medicine:

"Guidance for doctors who offer cosmetic interventions: General Medical Council June 2016

11. You must carry out a physical examination of patients before prescribing injectable cosmetic medicines. You must not therefore prescribe these medicines by telephone, video link, online or at the request of others for patients you have not examined."

Since the vast majority of health professionals view the use of remote prescribing of scheduled medications and treatments with medical devices for the purpose of cosmetic medical procedures as unacceptable and potentially dangerous, compulsory accreditation would require practices to follow the recognised standards of patient care that is determined to be appropriate by the profession and remote prescribing would be terminated.

Yet in 2015 AHPRA chose to delete the requisite of in-person, face-to-face consultation and instead published Option 3 of new guidelines for doctors performing cosmetic procedures <u>but expressly permitted remote prescribing.</u> Before and since that time, the practice of having a doctor with no experience in cosmetic medicine located in Melbourne or other capital city authorising nurses in shopping centre 'medi-spas' in Adelaide or other locations not regarded as remote and rural, or an urgent unmet in community need, has mushroomed. No doctor is available to take charge of any associated complication of treatment in these cases. Many such nurses have received two-day 'courses' from the manufacturer of the drugs, when registrars-in-training require months of supervision and mentoring.

Why did AHPRA ignore the profession's overwhelming objection to remote prescribing (IE via 'Skype', and now just by telephone with the patient in chain clinics in shopping centres)? Why did AHPRA ignore the British General Medical Council's ban on remote prescribing for cosmetic medical procedures?

The public is entitled to believe that they are protected by regulatory bodies such as AHPRA and the TGA. Yet this is far from the case. The public does not know that the practices outlined here are rejected by competent, experienced and ethical practitioners. In my opinion, in that way the sole purpose of AHPRA to protect the public has failed the public and put vulnerable patients at risk of serious harm as we have seen in several cases now.

Accreditation of facilities that provide cosmetic medical procedures would solve this problem.

Topic 3. Importation from offshore websites of products, both approved and not approved, which are medicines being obtained illegally;

3.1 How will compulsory accreditation help this problem?

3.1.1 Put very simply, accredited healthcare facilities must abide by the law or risk loss of accreditation status and therefore the license to provide services in cosmetic medicine be withdrawn

Topic 4 The limited effectiveness of AHPRA and the TGA to regulate delivery when they act on a purely reactive basis and may have limited powers under law to intervene even if informed of potential illegal activity

4.1 AHPRA is responsible to report and make recommendations on health regulation to COAG, in particular The Australian Health Ministers Advisory Council (AHMAC).

However, AHPRA has demonstrated that it declines to accept valid opinion from the profession, as seen according to the denial of the overwhelming support of the medical profession, both in Australia and abroad, to disallow remote prescribing . Therefore AHMAC is receiving invalid advice. The TGA is so under-resourced, it fails to police these matters.

In addition, the two bodies do not have appreciable communication with each other.

Example:

In 2015, the Dental Board of Australia (one of 14 Boards under AHPRA) published a Communique advising dentists that they were authorised to use Botulinum Toxin A for a condition known as temporo-mandibular dysfunction.

This is a condition involving the jaw joint. The DBA is not the vehicle that is permitted to authorise a prescription-only medication. Especially when such 'authorisation' is unlisted for that use by the TGA. The use of prescription-only medications in situations where there has been no TGA approval for that use is termed 'off-label'. In essence, AHPRA, via the DBA had unlawfully provided authorisation of a prescription-only medication to dentists. This author notified the TGA Complaints Dept and the Communique was immediately withdrawn by the DBA. However the Communique was replaced with a subsequent misleading statement which dental groups interpreted as 'it's ok as long as you can justify this application'. Yet there is no justifiable evidence on *how* to administer Botox for TMJ Dysfunction, what the dose is, what complications are found to occur, what side effects occur, and finally, Botox carries a warning in every box it comes in, that fatalities have occurred where Botox has been injected into salivary glands. These salivary glands are in close proximity to the TMJ. The DBA took it even further and permitted the teaching of dentists how to use Botox to treat frown lines, and other cosmetic medical uses, which surely is beyond the scope of practice of dentistry.

The present legislative instrument Health Practitioners National Law Act (2010) fails to provide AHPRA to make specific rules on the issues above. In essence it refers to Codes of Conduct and the direction that health practitioners abide by State ad Territory Legislation. Legislation that refers to the prescribing and administration of scheduled medications is the responsibility of each State and Territory Health Departments and ultimately the State Health Ministers.

To date, little or no satisfactory action has been taken by these organisations either.

No single body is prepared to act upon these issues.

4.2 How will compulsory accreditation help this problem?

As outlined in Topic 2, the fundamental principle of determining the Scope of Practice (SoP) of a health practitioner is called 'credentialing'.

In the example above the dentist proposing to use Botox for TMJ dysfunction would be required to request this procedure be added to his/her list of credentialed procedures. This process would require the dentist to provide evidence of the risks and complications of the treatment, and whether or not the proposed treatment was an approved application of the product by the TGA. In this particular instance, credentialing application to use Botox as an 'off-label' use where signficant risk has been demonstrated would not pass the accredited facility's credentialing process.

Health practitioners wishing to apply to perform procedures within an accredited healthcare facility must meet eligibility criteria which includes evidence of

recognised training, proof of experience, be in goodstanding and hold the necessary registration and insurance within their craft group. Once credentialed, the accredited healthcare facility is required to monitor performance and provide feedback to the practitioner and for the practitioner to demonstrate continuity of professional development and maintain their right to practice in accordance with Health Practitioners National law Act.

Compulsory accreditation ensures that only those practitioners who are successfully eligible and demonstrate this continuity will perform cosmetic medical procedures in the accredited healthcare facility.

Where a credentialed healthcare practitioner does not meet the required ongoing standard of care, the accredited healthcare facility has an obligation to prevent or correct this.

5. Conclusions

It is clear that the present effectiveness of the existing legislative instruments are ineffective and that the agencies responsible for regulation are not adequately resourced to implement them in any case.

The resources in such instances must be borne by those who gain profit from the industry involved. Compulsory accreditation standards determined by an authorised medical practice health standards body, such as the Australian Council on Healthcare Standards (ACHS) will require those who provide cosmetic medical procedures to provide evidence of a standard of care consistent with those recognised by the medical profession as at the very least, a minimum standard of patient care.

There is no cost to the public purse with this solution, and those whose practices do not meet the minimum standard of care according to accredited policies and protocols within the 2 year window period, would be required to cease performing any form of cosmetic medical procedure including the administration of scheduled prescription-only medications, and/or the use of medical devices that require approval from the TGA, whether they be performed by registered health practitioners or otherwise, until capable of doing so.

Attachments included with submission

Cosmetic Medical and Surgical Procedures, A National Framework: Final Report, Australian Health Ministers' Advisory Council 2011

Guidance for Doctors Who Offer Cosmetic Interventions, General Medical Council (United Kingdom) Published 12 April 2016, Comes into effect 1 June 2016

Public Consultation Paper and Regulation Impact Statement: Registered Medical Practitioners Who Provide Cosmetic Medical and Surgical Procedures, Medical Board of Australia, 17 March 2015

Guidelines for Registered Medical Practitioners Who Perform Cosmetic Medical and Surgical Procedures, Medical Board of Australia, 1 October 2016

Communique: Thirty third meeting of the Dental Board of Australia, Dental Board of Australia, 24 August 2012

Public Summary: Summary for ARTG Entry 67311 BOTOX botulinum toxin, type A purified neurotoxin complex 100U injection vial, Therapeutic Goods Administration, Produced at 23 July 2014 at 03:36:32 EST

Interim Policy: Use of Botulinum Toxin, Dental Board of Australia, 12 November 2010 (updated 28 October 2011)

Personal correspondence