



***ACAM Submission***

***to AHPRA***

***May, 2015***

***Consultation – Cosmetic medical and surgical  
procedures provided by medical practitioners***

***ACAM***

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This submission on the consultation document “Cosmetic medical and surgical procedures provided by medical practitioners” is made by **The Australasian College of Aesthetic Medicine (ACAM)**, which has a strong commitment to standards in medical practice and supports accreditation of cosmetic medical practices. We fully support the National Framework for Regulating Cosmetic Medicine and Surgical Procedures and welcome this initiative.

## **Background information about ACAM**

(<http://www.aestheticmedicine.org.au>)

The Australasian College of Aesthetic Medicine (ACAM) is a national organization of medical practitioners trained to high professional standards, whose main objective is to serve the community by providing high quality care, and aims to promote advancement, integrity and sound practice principles in the discipline of aesthetic medicine.

The specific aims of the College are:

- To promote the education of members and other persons directly associated with laser and cosmetic medicine activities, and of the general public concerning endeavours particular to the profession of cosmetic medicine.
- To promote the advancement of cosmetic medicine by providing a forum for expression of professional opinion on cosmetic medicine activities.
- To promote technical advancement by providing for professional education through lectures, industry displays and presentations and by the exchange of information to assist the development of cosmetic medicine.
- To promote sound cosmetic medical practice and integrity.
- To broaden professional relationships among members and to maintain and increase the prestige, standing and influence of cosmetic medicine.

At present, the College has 217 members, being 137 Full Members, 72 Fellows and 8 Associate Members.

Quality assurance and Continuing Professional Development is maintained through the Royal Australian College of General Practitioners (RACGP) for which the College is an accredited provider in the re-accreditation process for the Quality and Continuing Professional Development Programme.

The Australasian College of Aesthetic Medicine was formed in 2009 to give professional recognition to medical practitioners who have acquired further training and experience in Cosmetic Medicine.

Full Membership of ACAM is open to fully registered medical practitioners of good standing who have an interest in cosmetic medicine.

To obtain Fellowship of ACAM, members must:

1. Be current Fellows of another medical or surgical college recognised by the Australian Medical Council or the New Zealand Medical Council or international equivalent;
2. Have been Full Members of the Australasian College of Aesthetic Medicine (previously ASCM) for 24 continuous months, whose application has for Fellowship has been accepted by the Board of ACAM; and
3. Have satisfactorily completed the Diploma in Cosmetic Medicine or be medical practitioners who have been prominent in the field of cosmetic medicine and have accepted the Board's invitation to become Foundation Fellows.

Activities that the Australasian College of Aesthetic Medicine has initiated or supported include:

- An annual **Laser and Cosmetic Medicine Conference (LCMC)**. The upcoming 11<sup>th</sup> National Laser and Cosmetic Medicine Conference will be held in Queensland in November 2015 (<http://www.dcconferences.com.au/lcmc2015/>).
- **Diploma in Cosmetic Medicine**. A 12 month online tutorial program with logbook, written examination and viva examination.
- **Diploma in Laser Safety and Science** with written examination, logbooks and viva examination.
- Regular **cosmetic medicine workshops** every 6 months for medical practitioners.
- Subscription to the international journal, *the Journal of Cosmetic and Laser Therapy*, received by all our members quarterly.
- Regular **educational state meetings** on current cosmetic medicine topics.

ACAM has reviewed the Public Consultation and Impact Statement and supports option 3 in the Consultation Document, with some extra considerations.

ACAM would like to add to the recommended proposals with regard to three areas of the Guidelines:

1. Standards of practitioners performing on-surgical cosmetic medicine procedures
2. Standards of facilities where cosmetic procedures are performed
3. Mandatory face-to-face medical practitioner consultation before prescribing S4 cosmetic injectables

## **1. Standards of Practitioners Performing Non Surgical Cosmetic Medicine Procedures**

Many medical products used in cosmetic procedures, such as botulinum toxin (Botox, Dysport), hyaluronic acid (Juvederm, Restylane), Poly-Lactic Acid (Sculptra) other non-permanent fillers and lignocaine, are classified in the Poisons Schedule as S4 drugs. Their use is controlled in NSW by the Poisons and Therapeutic Goods Act (1966) in order to protect the health and welfare of the community.

The Act requires that S4 drugs be supplied only on the written prescription of a medical practitioner. The Act also restricts control, storage and dispensing of S4 drugs to medical practitioners and pharmacists.

Under the Act, a medical practitioner may supply an S4 drug to a nurse practitioner to subsequently administer to a patient, as long as the patient is under the direct care of the medical practitioner and written patient-specific authorisation to administer the drug has been given to the nurse.

A medical practitioner may NOT supply an S4 drug to a nurse for administration to a patient who is not under the direct care of that medical practitioner. A nurse may NOT administer an S4 drug to a patient unless written authorisation has been given by a medical practitioner to administer the substance to that specific patient.

### **Protocol for the use of S4 drugs in cosmetic procedures**

#### *i. Initial consultation with a medical practitioner*

The patient is assessed by the medical practitioner as for a normal medical consultation, including a clinical history, and a record of the patient's medications and allergies. A plan of management is decided and must include a discussion of potential side effects and complications of any procedures or drugs to be used. The patient must give informed consent before undergoing any procedures.

ii. *Administration of S4 drugs*

Once the medical practitioner has determined a plan of management, an appropriately trained and qualified nurse (see below) may administer S4 drugs according to the medical practitioner's written instructions. The medical practitioner's prescription should incorporate a maximum limit (eg, the number of units of Botox) and the specific area in which the product is to be used. The medical practitioner should be immediately contactable to deal with any problems that may occur related to the administration of the drug.

iii. *Medical practitioner review of the patient*

The medical practitioner must review the patient in the following circumstances:

- when a new S4 drug is to be used (eg, Restylane in a patient who has previously had Botox)
- when any adverse event or unexpected outcome of treatment occurs
- when more than 12 months has elapsed since the last medical consultation in which the S4 drug was prescribed

### **Minimum standards for nurses who administer S4 cosmetic drugs**

A nurse practitioner who administers S4 drugs should have:

1. Full registration with the Australian Health Professional Regulation Agency
2. A current certificate in cardiopulmonary resuscitation and competence to manage emergencies such as anaphylactic reactions to drugs
3. Appropriate training in safety and sterility protocols relevant to injections.
4. Training and certification for administration of each individual cosmetic product that is used. This training may be provided by the distributors of the products or other appropriate organisations, such as the Australasian College of dermal Science, or other medical bodies that offer a training programme for aesthetic nurses.

The nurse may only carry out the written instructions of the medical practitioner.

The nurse should record in the patient's notes how and where the S4 drug was administered,  
and the dose.

It is recommended that nurses do not inject permanent fillers such as poly-L-lactic acid (Sculptra).

## **Medico legal issues**

### ***Medical practitioners***

Medical practitioners who supply S4 drugs to nurses but have no input into the clinical management of the patient, or no physical presence on the premises at which the drugs are injected into the patient, are in contravention of the law and liable to prosecution.

It is recommended that medical practitioners check with their indemnity insurance company to ensure that any nurses employed by them to administer S4 drugs are covered by their policy.

### ***Nurse practitioners***

Nurses who function autonomously to store, prescribe and dispense S4 drugs purchased for them by medical practitioners are doing so in contravention of the law. This is outside the scope of nursing competency and practice.

Nurses who treat patients who have not been assessed by a medical practitioner prior to treatment are in contravention of the Poisons and Therapeutic Goods Act.

Nurses who perform injections of S4 drugs without a written prescription from the physician are contravening the law.

Nurses operating outside this advice may find they are not appropriately covered, either professionally or industrially, if a complaint is made by a patient. Most nurses do not have personal indemnity insurance, and instead rely on their employer's professional insurance. In the case of a complaint, the insurance company and the Nurses and Midwives Board would investigate whether the nurse was educationally prepared to perform the procedure and whether it comprised an appropriate scope of practice. If the nurse's actions were found to be inappropriate, the nurse may stand to lose his or her registration. The insurer may also decline to cover the nurse if the nurse's training for the particular procedure is not extensive and well documented, leaving the nurse personally liable for all legal expenses.

### ***Case Study: Nurse deregistered for injecting S4 drugs without adequate supervision 2***

A recent tribunal decision has cancelled the registration of a Sydney cosmetic medicine nurse, stressing the need to deter others from overstepping the bounds in injecting patients with restricted drugs such as Botox without adequate supervision. S4 medications were supplied and the nurse administered the drugs to clients at a day spa in Collaroy.

The nurse acted without the direct supervision of a medical practitioner and without authorised prescriptions. She breached a 2005 protocol governing the use of S4 (Schedule 4 – Prescription Only) drugs for cosmetic procedures by nurses.

The nurse was found guilty of professional misconduct and had her registration cancelled for three months and was ordered to pay costs.

The administration of Botox and dermal fillers is a medical procedure that must be medically supervised.

*Case Study: Plastic surgeon prosecuted for breaching Poisons and Therapeutic Goods Act*<sup>3</sup>

The Health Care Complaints Commission prosecuted a plastic and reconstructive surgeon, before a Medical Professional Standards Committee at an inquiry in October 2014.

The Complaint alleged that he had supplied Botox and dermal fillers (the drugs), Schedule 4 restricted substances under the Poisons and Therapeutic Goods Act 1966, to a registered nurse. The nurse administered the drugs to patients at his practice. It was alleged in the Complaint that the doctor:

- was unaware of the suitability of the drugs for the patients, as he had not seen the patients beforehand and did not have sufficient experience with the drugs
- did not provide his direction and approval to the nurse to use the drugs on specific patients
- did not provide supervision to the nurse while she administered the drugs to patients
- did not retain overall control of the safe and appropriate use of the drugs (the drugs were also taken out of the practice by the nurse)

On 19 December 2014 the Committee found all particulars proved, other than that the doctor failed to provide supervision to the nurse. It held that the term 'supervision' in the Poisons and Therapeutic Goods Act and by professional bodies was unclear. The Committee noted that the doctor breached the Poisons and Therapeutic Goods Act and he had an attitude of carelessness regarding the obtaining and handling of the drugs. However, the Committee did not find that the conduct amounted to unsatisfactory professional conduct.

## **2. Standards of facilities where cosmetic procedures are performed**

ACAM notes that both medical practitioners and nurses are performing non-surgical cosmetic medicine procedures outside the traditional medical setting. There are anecdotal reports of injections being performed in Beauty Salons and Hairdressing Parlours, as well as lounge rooms in people's homes.

This is clearly inappropriate. However determining what standards should be expected has difficulties. Australian General Practice Accreditation Limited (AGPAL), a provider of accreditation and related quality improvement services to general practices has previously been in discussion with ACAM regarding establishing standards for Cosmetic Medicine practices. Establishing such standards involves significant costs in implementation and in enforcing regulations. ACAM has attempted to introduce standards for facilities as a code of practice, but has not been successful to date.

Other organizations, for example the Cosmetic Physicians Society of Australasia, have a voluntary Standards program for their members.

### **3. Mandatory face-to-face medical practitioner consultation before prescribing S4 cosmetic injectables**

There are occasions when telemedicine is both necessary and desirable for the best medical management of a patient, particularly for urgent care of patients in remote areas. However, aesthetic medicine procedures are elective and non-urgent, and require careful assessment of the suitability of the patient for the proposed treatment. Documentation and responsibility are also important issues, as is the medico legal position and whether a doctor's medical defence organisation would provide cover for this sort of activity.

The ACAM does not endorse telemedicine for aesthetic medicine consultation purposes and is concerned that this practice, in many cases, is just legitimising the prescription for a fee. ACAM believes that doctors should be required to have face-to-face consultations with the patient before prescribing any cosmetic injectable treatments. Doctors must not prescribe cosmetic injectables remotely, including by phone, email, video-link or fax.

In 2012, the UK General Medical Council made the following statement about new guidelines for doctors prescribing Botox and other injectable cosmetic agents: "These are not trivial interventions and we are clear that doctors should assess any patient in person before issuing a prescription of this kind. So while remote prescribing may be the right answer in many situations, this is not one of them." "We recognise that patients can benefit from consultations with their doctor by email, phone, or video-link or fax and that is fine as long as it is done safely, but our new guidance makes clear that doctors must now not prescribe medicines such as Botox remotely".<sup>4</sup>

#### References

1. [http://www.aestheticmedicine.org.au/pdf/protocol\\_nurse.pdf](http://www.aestheticmedicine.org.au/pdf/protocol_nurse.pdf)
2. <http://www.hccc.nsw.gov.au/Publications/Media-releases/2014/Ms-Rosalie-Piper---reprimanded--suspended-and-conditions-imposed>
3. <http://www.hccc.nsw.gov.au/Publications/Media-releases/2015/Dr-Peter-Anthony-Haerstch---unsatisfactory-professional-conduct-not-proved>
4. <http://www.gmc-uk.org/publications/13687.asp>

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