

EXPERTS IN NON SURGICAL SOLUTIONS

# **RESPONSE TO**

# MEDICAL BOARD PUBLIC CONSULTATION PAPER AND REGULATION IMPACT STATEMENT DATED 17 MARCH 2015

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#### **FXFCUTIVE SUMMARY**

Juv'ae is pleased to comment on relevant sections of the Medical Board Public Consultation Paper and Regulation Impact Statement dated 17 March 2015.

The focus of our submission relates primarily to Question 17.7 of the Consultation Paper:

Should a medical practitioner be expected to have a face-to-face consultation (in person, not by video conference or similar) with a patient before prescribing schedule 4 prescription only cosmetic injectables? If not, why?

Through this submission we will demonstrate why video based consultations are proven and safe in patient consultations and administration of Schedule 4 drugs by:

- firstly showing that Juv'ae employs the highest standards of self-regulated patient care, and
- secondly, by detailing how this rigid discipline is reflected in all administrative (e.g. record keeping, patient) and clinical procedures which in turn are supported by formal, meticulously composed documentation.

Juv'ae also prides itself on its strict training, education and re-education programs which are employed to ensure all its clinical practitioners are abreast of the latest techniques and viewed as best-in-class by other practices and patients.

We contend that our business has grown on the back of an image and reputation that has been scrupulously based on positive results and testimonials from patients who enjoyed positive experiences. The high quality of our standards and service is reflected in the fact we have not had a single claim made against us since opening 7 years ago, nor have we ever had the need to make a claim on our professional indemnity insurance as a result of our services.

At Juv'ae we have conducted approximately 100,000 treatments over the past 7 years, without a single insurance claim by a patient or by self-generation, without litigation, and free of severe adverse reactions. Nor have we been advised of a single patient or consumer complaint against Juv'ae to any regulatory body.

A plethora of attachments to this submission (at Annexure I) demonstrate the extent to which the practice is governed administratively and clinically.

Juv'ae will be pleased to discuss the contents of this paper and its underlying business operations with any authority seeking to cite evidence of the statements recorded herein.

Furthermore, we welcome involvement in development and testing of new regulations, guidelines and practices relating to delivery of non-surgical cosmetic procedures.

For ease of reference and distinction of purpose, this document has been divided into two separate parts:

- **Section One**, reflecting the current Juv'ae business model, practices and policies, standards and patient protections; and
- **Section Two**, providing specific responses to questions posed by the Medical Board, as relevant to the Juv'ae practice business.

#### SECTION ONE – JUV'AF PRACTICES AND POLICIES

#### 1.0 ABOUT JUV'AE

Juv'ae is a company specialising in *non-surgical cosmetic procedures*. Juv'ae is not involved in plastic surgery or reconstructive surgery. However, in respect of Services listed on our website titled 'Surgery', we refer patients seeking such surgical operations to known expert practitioners. Those Cosmetic Surgery specialists operate from their own premises, totally free of any commercial agreements, partnering arrangements or financial returns to Juv'ae.

This specific distinction in respect of our non-surgical procedures is vital and relevant to the views expressed herein as certain sectors of the cosmetics industry may deserve different levels of regulation, accountability and supervision.

#### 1.1 Geographic Reach

Juv'ae performs the aforementioned procedures in 76 clinics across NSW, Queensland, Victoria and A.C.T. Juv'ae is a member of the College of Registered Nurses. Our business model is based on attendance by our staff at leading beauty clinics, renting space from them on a sessional basis, and providing our services from those clinics in strict accordance with our policies, practices and standards.

Procedures performed by Juv'ae are minor (non-surgical) and do not involve cutting beneath the skin.

The abovementioned procedures are reversible if a patient so desires or are temporary and therefore low risk to consumers.



#### 1.3 Cosmetic Doctor Oversight by Tele-health

By leveraging technological advances in the medical/health industry, 'tele-health' in particular, we have engaged the power, effectiveness and convenience of patient treatment management by employing the services of qualified Cosmetic Doctors who oversee consultations via Skype (video conference). In rare instances where technology or communications are not functioning to acceptable standards, patient treatment does not proceed until all electronic facilities are fully recovered.

Four Medical Practitioners (2 contract, 2 employed) attend treatments employing Tele-health technology (Skype). However, if a Doctor is required to attend on the premises, he/she will be made available within an hour in NSW, Queensland, Victoria, and within 4 hours in A.C.T.

Screen resolution provides the attending doctor with a clear image of the patient's face and other areas of treatment. The attending Doctor is afforded a clear vision of the patient's muscle contractions, movement and volume loss. Consistent with our principles of continuous improvement, any emerging enhancements in technology will be incorporated into the process. Further procedural detail and the supervising doctor's actions during patient consultations is explained in Section 3.1 Appointments & Consultations.

We are not aware of any risks reported by the TGA or other authorities in respect of Skype/video based consultations. Furthermore, our tele-health records are fully auditable - treatment and medication details are recorded on patients' files for subsequent review as required at the time of the video consultation. Furthermore, entries in the *Adverse Reactions Register have not reflected any mishaps* (other than some expected side-effects of treatment e.g. bruising) that could be reasonably connected to remote supervision by Skype. Our Adverse Reactions Register template is attached at Annexure A.

As an ultimate test of the technology's efficiency, we note that *not a single complaint has been received or concern expressed* that has been related back to a doctor's patient management via Skype.



#### 2.0 STANDARDS AND REGULATION

Despite general lack of regulation in the cosmetics industry, since its inception Juv'ae's owners' personal morals and values dictated that high standards of self-regulation would be essential in respect of patient care, administration and clinical standards, always aspiring to achieve best practice, even when formal industry wide protocols do not exist. Patient care has always been the myopic focus of Juv'ae's ethical standards. We contend that our progress and success has been based on high quality products and services, reputation, and a business model closely aligned with its owners' morals and patient care ideals. Juv'ae does not service patients under the age of 18 and patients under 20 are treated with greater caution and under the usual supervision of a doctor, after which the rigid procedures detailed in 3.1 Appointments & Consultations are complied with. Refer Annexure B for our Refusal of Treatment Policy.

A comprehensive Policy & Procedure Manual, composed by Juv'ae, is regularly updated to ensure strict compliance with highest standards of medical practice is maintained at all times. This Manual is not an industry dictated document and we acknowledge that contents may vary between industry operators. A list of the contents of our Manual is attached at Annexure H.

We believe that our self-imposed code of conduct complies with, and in fact exceeds, those contained in the Medical Board of Australia's Good Medical Practice: A Code of Conduct for Doctors in Australia 2014.

#### 2.1 Board Identified Options

In respect of the four possible remedial options identified by the Board, our comments are detailed in Section Two of this submission.

In general, we believe that transition from self-regulation to regulation should be gradual, recognising proven, existing practices as the industry's concern is that sudden over regulation could severely impact both practices and consumers, thereby limiting provision of an increasingly popular service.

Primary reasons for this comment, particularly in respect of the supervision and management of patients by wide ranging changes, e.g. as implemented in the UK, will negatively impact the local industry due to:

- limited numbers of general practitioners in Australia as is already evident in the ability of GPs to meet the demand in primary healthcare; and
- any requirement for a medical practitioner to conduct face-to-face consultations will impose a
  severe cost on practices which will ultimately increase treatment prices to consumers. As an
  example, Juv'ae will have to engage about 17 medical practitioners to administer face-to-face
  consultations, rendering the entire business, and probably most others, unsustainable.

The Juv'ae cost model, based on demonstrated clinical standards and proven results, is already more expensive than practices who do not apply the same level of rigour.

In summary, we strongly suggest that all relevant industry and government authorities must make serious efforts to embrace the power and progress of technological advances in Australia to facilitate (and enhance if possible/necessary) the employment of remote patient management as Juv'ae has successfully achieved in delivery of non-surgical procedures.

#### 3.0 PATIENT PROTECTIONS

#### 3.1 Appointments & Consultations

details the following comprehensive steps,

including patient education:

• Cooling off: Patients who contact the practice to pre-book a consultation are provided with medical and financial information (website & hard copy literature) and requested to consider all information, including their decision to be treated, prior to confirming an appointment, thereby affording them an opportunity to

fully understand the process, consider risks and seek another opinion e.g. from their partner, doctor etc – a self-imposed, pseudo 'cooling off' period;

- A *Registered Nurse assists the patient* to complete a Medical History and review the Consent Form. Refer Annexure D for consent forms used by Doctor, Nurse and for Patient;
- The Nurse prepares an individual Patient Treatment Plan;
- Cosmetically Trained Doctor is contacted via Skype (or face-to-face in the rare event that Skype fails), employing conventional tele-health practices;
- If all forms of technology or communications fail, the treatment does not proceed;
- Cosmetically Trained Doctor reviews the Medical History, Consent Form and Treatment Plan with the patient and the Nurse via Skype, explaining each in detail once more, *confirming the patient's understanding of all aspects including potential risks*;
- Cosmetically Trained Doctor also examines the patient's face via Skype;
- Cosmetically Trained Doctor determines treatment and frequency of dose;
- Cosmetically Trained Doctor then asks to see the signed Consent Form via Skype;
- Cosmetically Trained Doctor *writes a prescription*, immediately e-mailed to the nurse and uploaded to the patient's individual Medical Record;
- Cosmetically Trained Doctor signs off the Treatment Plan;
- The Nurse draws the vials for administering under the supervision of the Doctor;
- Cosmetically Trained Doctor will Skype in with the Nurse for all subsequent treatments and also with the patient where the dose varies or there are any changes in the patient's condition e.g. pregnancy, adverse reaction; and
- An *Emergency Kit is mandatory at each site* containing, inter alia, adrenalin epi-pens for use in the unlikely event of anaphylactic allergic reaction and hyalase to reverse dermal fillers where required. Each consultation process demands the Emergency Kit must be shown to the Skype Doctor before treatment commences on every occasion.

We refuse to treat patients where the doctor feels they suffer with body dysmorphic disorder. Such patients are encouraged to see a GP in regard to the condition. Refer Annexure B.

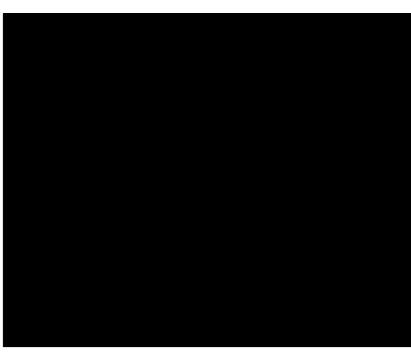
#### 3.1.1 Walk-ins

"Walk ins" are potential patients without an advance appointment for consultation. This group is also afforded the same opportunity to fully familiarise themselves with all aspects of the planned procedure as described above.

A Nurse will present the customer with the same information brochures, go through all aspects of the selected treatment including risks or possible reactions. Subsequently, the Doctor goes through the details of the treatment and potential risks once again before the patient is asked whether they still wish to proceed.

As our procedures are reversible or temporary, should a patient be dissatisfied with the treatment result, we willingly reverse the procedure with hyalase filler and refund their payment in genuine cases.

#### 3.2 Patient Education



Literature is provided to patients on attendance and when making telephone or online bookings.
Section 3.1 Appointments &
Consultations also refers to the important 'cooling off period'.
Typical questions posed by aspiring patients are listed below, including a summary of responses and brochure information:

What does the procedure involve? Details of physical procedures are described in clinical, practical terms.

What is the recovery like? Honest opinions are expressed based on actual evidence and experience.

How many injections/treatments will I need? Responses, including individual condition dependencies, are explained.

How long will the results last? Patients are provided with pragmatic responses including possible necessity for repeat treatments, if applicable.

What about recovery? As above, responses are based on evidence and experience gleaned over several patients/years.

What else do I need to know? Potential adverse reactions are explained openly and honestly so patients have no false illusions of possible risks.

A copy of the leading pharmaceutical company Allergan's information brochure is attached at Annexure E.

#### 4.0 TRAINING

Any GP may attend a brief 2 hour training course (introduction to Botox etc) and enter the industry without proper readiness to service patients. Following employment at Juv'ae, we insist on subjecting all our doctors and nurses to rigid training programs prior to treating patients. Refer attached testimonials at Annexure F which evidence this statement.

A strictly observed training regimen for Juv'ae Doctors and Nurses comprises:

- 8 hours with a qualified Cosmetic Doctor;
- 2 weeks full time with a Clinical Specialist from the Pharmaceutical company and one of our Nurse Managers; and
- 1 day every month and 4 hours every fortnight with one of our Nurse Managers.

Training Doctors and Nurses at Juv'ae are assigned 'shadow' duties for a minimum 8 hours with a fully qualified Doctor until they have personally witnessed the treatment of at least 10 patients in each treatment (Botox and Dermal Fillers), only after which they are permitted to service patients. There is also a Clinical Specialist from the pharmaceutical company on site.

As part of each Nurse's Personal Development Plan, they will eventually become eligible to undergo Nurse Practitioner training paid for by Juv'ae. We currently have 3 Nurses eligible to commence this training in the next 12 months.

We mention that in August 2015, the entire clinical team at Juv'ae will be attending a Cosmetics Conference in New Zealand as part of our efforts to remain abreast of current and emerging trends, practices and developments in the industry.

The cost of this training regimen is considerable and truly differentiates better structured practices from more cost conscious practices who rely on lower prices for competitive edge. However, Juv'ae believes that the reputation it has developed for prioritising patient health care over cost factors has been far more satisfying and rewarding.

The Cosmetics sector is generally self-regulated and there are rumoured, unscrupulous operators, referred to as 'nail artists', who give the sector a bad name and expose patients to unnecessary risks.

#### 5.0 RISK MANAGEMENT

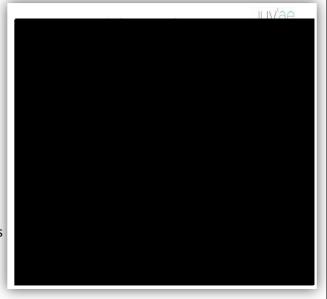
Consistent with Juv'ae's owners' personal values and principles, we understand that oversights or incidents beyond our control, including potential patient reactions to certain treatments, may pose risks and exposures which must be addressed as soon as possible.

Accordingly, Risk Management plans for clinical policy and practice procedures, are aimed at devising appropriate measures to address or avoid as many of such incidents as may be anticipated. Examples are:

- Patient treatment policy: We do not service patients under 18 (refer Section Two response to Q 17.2) and patients under 20 are only serviced with extra caution. Refer Annexure B;
- Emergencies:
  - Each staff MUST carry an Emergency Kit, accessible during every consultation and presented to the attending Doctor at consultation commencement;
  - o An ambulance MUST be called in the case of an emergency not been required in 7 years;
  - An Adverse Reactions Register (Refer Annexure A) MUST be kept to address adverse reactions (e.g. rash) and a doctor MUST be called upon to check an adverse reaction on every occasion;
  - o A 24/7 Emergency Line is available to Juv'ae patients only accessed once in 2 years; and
  - o If a Doctor is required to attend in person on premises, he/she will be made available.
- Nursing Standards: Each Nurse's performance/practices are reviewed by a Nursing Manager every 6 weeks to ensure they are complying with Juv'ae's best practice standards;
- Escalation: Juv'ae has a documented Escalation
   Procedure if a query deserves urgent attention or
   a doctor's personal presence. Nothing is taken
   lightly or allowed to be treated with less urgency.

We mention with pride that Juv'ae has never had a single insurance claim in 7 years.

We also note in passing that the ban on advertising S4 drugs (e.g. botox) limits the ability to enhance patient education.



#### 5.1 Adverse Reactions Management

Of the patients Juv'ae treat each month only a small percentage (roughly 0.05%) may experience side effects, usually minor and in accordance with previously explained possible side-effects e.g. bruising, all of which are taken seriously and recorded in the Adverse Reactions Register until addressed. As above, any serious issues will be addressed by a Doctor, face-to-face if required.

Follow up consults are provided free of charge for patients suffering adverse reactions. The doctor performs the follow up consultation via Skype at no cost. If a Doctor is required to attend in person on premises, he/she will be made available.

As a further source of comfort for patients, we mention that, subject to a patient's preference, Dermal Fillers are reversible and Botox is temporary, lasting approximately 3 months. No 12 month scripts are issued and patients are required to attend a Doctor consultation whenever medications are needed.

#### 6.0 SUMMARY

The stringent procedures and processes we have voluntarily imposed on our practices, our clean claims record and risk management strategies bear strong evidence of the fact that consultations for minor procedures do not require personal face-to-face attendance by a medical practitioner. Furthermore, our record of successful treatments under strict, video controlled supervision by a qualified doctor, bears further evidence of the safety, effectiveness, affordability and convenience of the process.

Our self-imposed code of conduct goes beyond that suggested by the Medical Board of Australia's Good Medical Practice: A Code of Conduct for Doctors in Australia 2014.

Tele-health already exists in the health industry with the Medicare Benefits Schedule even providing Item Numbers for certain tele-health attendances. With the need to reach out to remote communities and an ageing population that makes it more difficult for immobile patients to attend their doctor's premises, Australia is focusing more on tele-health products and services throughout the health industry. As a result, we submit that the question should not be whether to endorse consultations via Skype but rather to focus on how we can continue to ensure the integrity of video based consultations.

We believe Juv'ae's procedures are very good examples and we offer our services in drafting relevant procedures and standards in this regard.

It is alarming to note that Schedule 8 drugs are regularly administered directly by patients themselves at home, for example Pethidine, but that the administration of Schedule 4 drugs by a skilled nurse under the close supervision via Skype (or other on-line means) of a qualified and highly trained medical practitioner is being questioned.

The self-imposed processes set out in Section One of this submission translate to a lower profit margin for Juv'ae than other less stringent competitors. Juv'ae has a strong social conscience and sincerely believes in the need to prioritise patient safety above profit at all times. We believe this is the reason for our success.

#### SECTION TWO - RESPONSES TO MEDICAL BOARD CONSULTATION PAPER

#### 1.0 INTRODUCTION

As demonstrated in Section One, Juv'ae operates its clinics in accordance with high, self-regulated standards focused on the health and safety of its patients. Standard procedures include availability of comprehensive patient literature on all relevant aspects of various treatments, affording them adequate time (cooling off period/opportunity) to reconsider or consult other sources on their decision, if appropriate.

Accordingly, we have provided the following responses to Medical Board questions which are most relevant to Juy'ae's business model. Our views on proposed options for the Cosmetics industry are expressed below.

#### 2.0 CONSULTATION QUESTIONS & JUV'AE RESPONSES

1. Do you agree with the nature and extent of the problem identified in this consultation paper, for consumers who seek cosmetic medical and surgical procedures provided by registered medical practitioners?

**Juv'ae Response:** Generally yes, but more so in regard to delivery of *cosmetic surgery* services and not the minor non-surgical sector. Based on our history, supported by rigid standards, principles and results, we have not experienced the level of patient risks described in the Paper.

2. Is there other evidence to suggest that there is a problem with consumers making rushed decisions to have cosmetic medical and surgical procedures provided by registered medical practitioners without adequate information?

**Juv'ae Response:** Based on hearsay and verbal feedback, there is an increasing number of consumers deciding to undertake cosmetic procedures. However, our information indicates that rushed decisions usually occur where practitioners do not honestly disclose risks involved with surgery or where they play down the risks, exploiting patients' emotional desire to improve appearance, confidence, personality etc.

Some 'Nail Artists' provide minimal to no educational information to the patients they treat. We also make mention once again that the restrictions on advertising the use of Schedule 4 drugs makes it harder for providers to educate patients initially.

Juv'ae highlights the risk and side effects to all patients and it is explained by the nurse first then the Doctor to ensure the client has sound knowledge of risks and side effects.

3. Is there other evidence that consumers cannot access reliable information or are relying on inaccurate information when making decisions about these procedures?

**Juv'ae Response:** Information of varying quality is available to consumers. However, in the absence of common, agreed, or a centrally supervised source of information, practices bear the responsibility of providing information for consumers, resulting in a variety of information quality. Even if information is not produced with intent to deceive, it may be inaccurate and/or unreliable in some instances.

4. Is there evidence that inappropriate use of qualifications and titles by medical practitioners may be misleading for consumers?

**Juv'ae Response:** Yes. Medical practitioners who attend a 2 hour course in Botox and Fillers at a Pharmaceutical company are prematurely free/qualified to treat patients. However, as indicated in Section One 4.0 Training, whenever a practitioner with such a background approaches Juv'ae for employment it is

mandatory that he/she undertakes far more comprehensive training before being permitted to treat patients. Training continues on a fortnightly and monthly basis until they cease employment with Juv'ae.

Juv'ae injecting nurses are required to undergo a vigorous compliance and competency test which is monitored regularly. No nurse is permitted to inject out of her scope (authorised level of competency). Juv'ae to date has not injected patients of high risk areas such as noses, temples and glabella which are undertaken by the Cosmetically Trained Doctor or Nursing Managers who are suitably qualified and authorised.

5. Is there evidence that offers of finance for these procedures may act as an inducement for consumers to commit to a procedure before they have had adequate time to consider the risks?

**Juv'ae Response:** Juv'ae performed anti-wrinkle treatment and dermal fillers are relatively lower priced items and patients generally do not require finance to have these treatments as they would if they were undergoing surgery such as breast augmentation.

Juv'ae has a facility with Medical & Cosmetic Credit Pty Ltd who provide finance for medical, dental and cosmetic services. Since the arrangement commenced 4 years ago, we are only aware of 1 loan being taken out. While it provides earlier financial assistance (subject to lending/repayment criteria), we do not believe it promotes premature or inappropriate commitment to a procedure before they have adequate time to consider risks. The approval process for a loan itself takes a minimum of 24 hours providing a pseudo cooling off period.

6. Is there other evidence of disproportionate numbers of complaints or adverse events for consumers who have had these procedures?

**Juv'ae Response:** The Cosmetics industry is growing steadily which means there is a significant increase in services provided. With a growth in services provided, it is to be expected that the number of complaints will also rise. However, we do not feel the number is disproportionate to the number of services provided. As indicated in Section One, in regards to Juv'ae's business, the percentage of complaints to treatment volumes are negligible and thoroughly addressed until totally resolved.

Juv'ae has not experienced severe adverse or unmanageable reactions to date and believe this treatment can be offered to patients in a safe manner if processes, training and TGA approved protocols are followed.

7. Is there other evidence to identify the magnitude and significance of the problem associated with cosmetic medical and surgical procedures provided by registered medical practitioners?

**Juv'ae Response:** We are not aware of statistical evidence in this regard, particularly in relation to non-surgical procedures.

8. Is there other evidence that the current regulation of medical practitioners who provide cosmetic medical and surgical procedures is not adequately protecting consumers

**Juv'ae Response:** Hearsay and verbal rumour suggest the current level of regulation of medical practitioners who provide cosmetic surgical procedures does not adequately protect consumers.

9. Does the Board's current code of conduct and the existing codes and guidelines of the professional bodies provide adequate guidance to medical practitioners providing cosmetic medical and surgical procedures?

Juv'ae Response: We believe the codes and guidelines are adequate, provided they are complied with.

# 10. How effective are existing professional codes and guidelines in addressing the problem identified by the Board?

**Juv'ae Response:** We believe they are adequate as a baseline standard. However, as stated in Section One, Juv'ae applies a code of conduct which, in our opinion, exceeds those dictated by the professional codes and guidelines.

11. Would consumer education material be effective in addressing the problem? If so, how could it be designed to ensure it is effective and kept up to date and relevant?

**Juv'ae Response:** Yes, provided it is composed by an independent, unbiased, empowered authority that will consult the industry on progressive updates to ensure relevance and consistency with emerging technologies and practices. *Juv'ae welcomes involvement in such an initiative*.

12. Who do you think is best placed to design consumer education material about cosmetic medical and surgical procedures provided by medical practitioners?

**Juv'ae Response:** An independent, unbiased, qualified Specialist with considerable experience in the Cosmetics industry, possibly engaged and overseen by authorities such as the Australian Health Practitioner Regulation Agency and/or Office of Best Practice Regulation. However, we cannot stress strongly enough that ongoing consultation with various representative organisations in the cosmetics and medical sectors should be a necessary pre-cursor to introduction of regulations or legislation.

17.1 Should there be a mandatory cooling off period for adults considering a cosmetic medical or surgical procedure (other than for minor procedures)? If so, is seven days reasonable?

**Juv'ae Response:** Juv'ae only performs minor, non-surgical, procedures and this question does not apply but we are of the view that a cooling off period would be beneficial. However, as described in Section One, we nonetheless offer a cooling off period even for minor procedures, allowing patients sufficient time to consult other friends/advisers prior to finalising their decision.

17.2 Should there be a mandatory cooling off period for patients under the age of 18 who are considering a cosmetic medical or surgical procedure? If so, is three months reasonable?

**Juv'ae Response:** We are not in a position to respond as our policy is *not to treat patients under the age of 18.* In our opinion, patients under 18 are less capable of consistently providing informed consent, dependent on each individual's level of maturity and capacity to understand the information or the potential risks/impact of their decision to proceed with treatment.

Even patients under the age of 20 are only treated at Juv'ae with extra caution. A cooling off period would be beneficial for this particular age group.

17.3 Should medical practitioners be expected to assess patients for indications that the patient has significant underlying psychological problems which may make them an unsuitable candidate for the procedure?

**Juv'ae Response:** We agree with this suggestion for surgical procedures. You will note even though we do not perform surgical procedures, our doctors still actively identify patients they believe may suffer from body dysmorphic disorder and encourage them to consult their GP in this regard.

17.4 Should medical practitioners be expected to refer these patients to an independent psychologist or psychiatrist for evaluation?

**Juv'ae Response:** Yes, where surgery is involved, particularly for patients below 20. We do not feel this is necessary for minor procedures given the fact that dermal fillers are reversible and botox is temporary.

17.5 Is it reasonable to expect that registered medical practitioners refer all patients under the age of 18 to an independent psychologist or psychiatrist for evaluation before a cosmetic medical or surgical procedure is performed, regardless of whether legislation exists (as it does in Queensland via the Public Health Act 2005)?

Juv'ae Response: We prefer not to respond as it is against our policy to treat patients under the age of 18.

17.7 Should a medical practitioner be expected to have a face-to-face consultation (in person, not by video conference or similar) with a patient before prescribing schedule 4 prescription only cosmetic injectables? If not, why?

**Juv'ae Response:** We believe video based patient consultation via Skype or similar technology, supported by effective technological evidence (e.g. real time images of face transmitted to supervising doctor), are sufficiently thorough to obviate the need for face-to-face consultation prior to prescribing Schedule 4 injectables. In Section One we have detailed our strong support for leveraging this powerful, effective and convenient means of tele-health. Additionally, we have also stated that *not a single complaint or unmanageable adverse reaction has been reported* by any patient who has received oversight care by a 'Skype Doctor'. We reiterate the government has already approved of this technology by making MBS item numbers available for such attendances in certain circumstances.

At Juv'ae we have conducted approximately 100,000 treatments over the past 7 years, without a single insurance claim by a patient or by self-generation, without litigation, and free of severe adverse reactions. Nor have we been advised of a single patient or consumer compliant to any regulatory body. This is an indication that Tele conferencing is effective, safe and as good as face-to-face consultations in respect of patient care and dispensing/prescribing of medication.

27. Which option do you think best addresses the problem of consumers making rushed decisions to have cosmetic procedures without adequate information?

#### Juv'ae Responses:

• Option one – Retain the status quo of providing general guidance about the Board's expectations of medical practitioners providing these procedures via the Board's approved code of conduct

Juv'ae Response: merely recognising the status quo is not effective nor fair to consumers;

Option two – Provide consumer education material about the provision of cosmetic medical and surgical procedures by medical practitioners

**Juv'ae Response:** education alone, regardless of uniformity and comprehensiveness, is fully supported but insufficient as a standalone measure.

• Option three: Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines that clearly articulate the Board's expectations of medical practitioners

**Juv'ae Response:** strengthening of current guidance is desirable. However, excessive introduction of complex legislation and regulation could render services too costly for practices and consumers, not to mention the fact that there is a lack of medical practitioners available to meet current patient demands.

• Option four – Strengthen current guidance for medical practitioners providing cosmetic medical and surgical procedures through new, practice-specific guidelines as per option 3 but which provide less explicit guidance to medical practitioners

**Juv'ae Response:** this option appears to be the most practical as it aims to introduce legislation, regulation and supervision in an orderly manner which may not negatively impact practices or consumers.

In general we believe *guidelines for the cosmetic surgery field need to be strengthened*. As there is minimum risk involved with minor, non-surgical cosmetic procedures, we feel our current self-imposed processes maintain the highest level of quality control and safety for our patients. We believe our processes would form a good mandatory basis for the minor (non-surgical) cosmetics industry.

• Other – please specify.

**Juv'ae Response:** We understand that some GPs provide primary health care medical treatment and also perform certain cosmetic procedures e.g. botox which may result in confusion or inappropriate use of the Medicare and private health systems. Furthermore, it is difficult for consumers to determine whether such practitioners are appropriately qualified or experienced to perform the procedures. There ought to be a clear, definitional distinction to avoid such potential overlaps, supported by appropriate qualification standards and expectations required of practitioners who provide both types of services.

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ANNEXURE C	
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<u> </u>	

# ANNEXURE D

# Consent Forms

Part I: Juv'ae Doctors
Part II: Juv'ae Nurses
Part III: Juv'ae Patients

ANNEXURE E				
Allergen Information Brochure				
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ANNEXURE F	
Testimonials	
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ANNEXURE G
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#### ANNEXURE H

## Policy & Procedure Manual Contents

- o Best Practice for Botulinum toxin type A and Dermal filler injections by nurses in Australia
- o Regulations Regarding Botulinum toxin type A Injection By Nurses in Australia
- o Botulinum toxin type A Training at Juv'ae
- o Clinical settings for professionals injecting Botulinum toxin type A and hyaluronic acid
- Disposing of waste products safely
- Personal hygiene
- o Writing a prescription for a Schedule 4 drug
- Storage of S4 drugs
- o Administering the medication
- Handling Complaints
- Skype Protocol
- o Protocol for Hyalase injection
- o Injection technique
- o Protocol for Ischaemia to an Artery
- Protocol for Anaphylaxis
- Cold chain process

#### **ANNEXURE I**

## Various Attachments

#### **Attachments:**

- 1. Post Care Instructions
- 2
- 3. Hyalase Protocol
- 4. Patient Information & Medical Record
- 5. Patient Consent to Hyalase
- 6. Patient Consent to Hyalase and Script
- 7.
- 8.

# ADVERSE REACTION REGISTER

	ORIGINAL			REGULAR				PATIENT		
COMPLIANT	TREATMENT	TREATING		PATIENT	EMAIL TO	PATIENT PHOTOS	FOLLOW UP	PHOTOS SENT		
DATE	DATE	INJECTOR	NAME	YES/NO	PATIENT	RECEIVED	DATE	TO INJECTOR	Complaint	FOLLOW UP ACTIONS

**CLOSED DATE** 



#### **Refusal of Treatment**

Juvae has the right to refuse patient treatment. If a doctor or nursing injector feels that the patient should not be treated, they are able to refuse treatment based on their medical judgement.

Any patients under the age of 18 years (even with a parents written consent), pregnant (or trying to get pregnant), breastfeeding or under the influence of alcohol/drugs will be refused treatment immediately.

Any patients who are identified with body dysmorphic disorder will also not be treated by nursing injectors.

Patients that are banned from treatment have a 'do not treat – banned' alert on their records in Simple Salon. If they refuse to accept this then a call is made to the for further clarification.



# Medical Officers Patient Consent and Script Form

☐ Entered into SS

Script emailed to injector



Patient Medical History & Contact Details \_\_\_\_\_ Referring Doctor Referring Clinic First name \_ Treating Nurse Surname Expiry of Consent \_\_\_\_/\_\_\_\_/ Date of birth Have you had Botulinum toxin type A or Dermal Filler Treatment before? If yes when/where/area/reaction\_\_\_\_\_\_ per no Have you had Permanent fillers? ∏no Are you prone to cold sores? □ yes □no Are you a smoker? ☐ yes no Have you had a Alcoholic drink today? If Yes □ yes □no Do you have any allergies? If Yes please describe \_\_\_ no ☐ yes Are you allergic to any blood products or local anaesthetic? \_\_\_ yes ∏no Are you pregnant/breast Feeding/ intending to become pregnant/IVF treatment? \* ∏no yes Do you take herbal supplements/ blood thinning medication (fish oils, aspirin, NSAIDs, Heparin, Warfarin)? ☐ yes no Have you had any facial surgery (including minimally invasive facial procedures (threading, implants) in the last 12 months? \_ \_ \_ yes no Do you have any other pre-existing or current medical conditions? \_\_\_ ∏no no Do you suffer from \*Neurological Disorders or Neuromuscular Disease such as Autoimmune disease, Myasthenia gravis, Eaton Lambert syndrome, muscular weaknesses? yes no Prescription and Plan for injection of Botulinum Toxin Type A & Hyaluronic Acid Dermal Filler **Product** Area to be treated <u>Dose</u> <u>Dose</u> Frequency/Repeats Top up <u>Botox</u> **Dysport** ☐ Crow's feet 10 - 400 10 - 900 3-6 monthly 2-4 weeks Frown 10 - 40010 - 9003-6 monthly 2-4 weeks Forehead 10 - 400 10 - 900**Botulinum Toxin** 1.5-2 monthly 2-4 weeks Chin/Gummy 02 - 12002 - 3001.5-2 monthly 2-4 weeks Type A Upper lip 02 - 120 02 - 300 1.5-2 monthly 2-4 weeks Brow lift 50 - 150 u150 - 300u 3-6 monthly 2-4 weeks **Hyperhidrosis** 20 - 60u 50 - 9003-6 monthly 2-4 weeks Masseters All of the above Lips 0.5 - 1 mls $0.5 - 1 \, \text{mls}$ 1-24 monthly 2-4 weeks N/Labials 0.5 - 1mls 0.5 - 3mls 1-24 monthly 2-4 weeks Forehead 0.5 - 1 mls1-24 monthly 0.5 - 1 mls2-4 weeks 0.25 - 1 mls0.25 - 1 mlsFrown/brow 1-24 monthly 2-4 weeks Dermal Filler 1-24 monthly 0.5 - 4mls0.5 - 4mlsMarionette 2-4 weeks Hyaluronic Acid 0.5 - 4mls0.5 - 4mls1-24 monthly Cheeks 2-4 weeks Hands 0.5 - 3mls0.5 - 3mls1-24 monthly 2-4 weeks Dermal Filler 0.5 - 2mls0.5 - 2mlsOrbital Rim 1-24 monthly 2-4 weeks Hvaluronic Acid Nose 0.5 - 1 mls0.5 - 1 mls1-24 monthly 2-4 weeks Jaw 0.5 - 3mls0.5 - 3mls1-24 monthly 2-4 weeks All of the above Lidocaine 0.5 - 3mls 0.5 - 3mlsAs required As required Initial Treatment Plan Date: Doctors Signature: Reviewed Treatment Plan Date: Doctors Signature: \_\_ Notes regarding review: Skype call made to

Uploaded to icloud



Date: \_\_\_\_\_

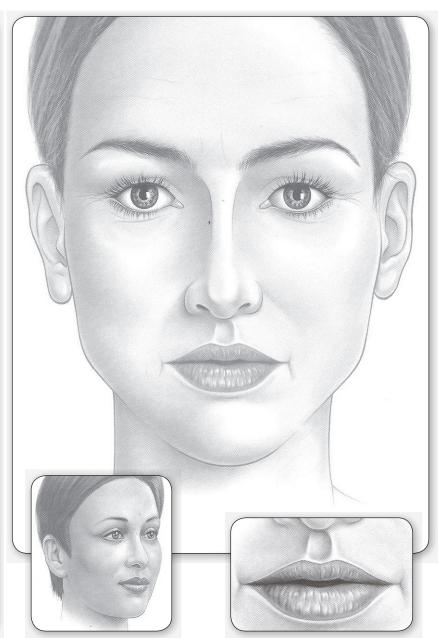
Patient Information Contact Details				
First name  Surname	Treating Nurse  Expiry of Consent			
Date of birth/	EXPITY OF CONSON			
Patient Information Medical History				
Have you had Botulinum toxin type A or Derma Filler Treatment Do you have any allergies including blood products or local ar If yes please describe	nesthetic?	□ yes	□ no	
Are you pregnant/breast feeding/ intending to become pregn Do you take herbal supplements/ blood thinning medication (a If yes please describe	aspirin, NSAIDs, Heparin, Warfarin)?	□ yes	□ no	
Are you currently suffering from any sinus infections?  If yes please describe		yes	□no	
Have you had facial surgery or recent dental procedures?  If yes please describe		yes	no	
Are you planning to have any waxing, laser treatment or skin reface area today?	esurfacing treatments to your	yes	no	
Do you have any other pre-existing or current medical conditions of the pre-existing or current		yes	no	
Do you suffer from *Neurological Disorders or Neuromuscular D disease, Myasthenia gravis, Eaton Lambert syndrome, muscula		yes	□no	
*If you have answered YES to any of the questions marked with	* you will not receive treatment toda	ay.		
Risk and side effects Botulinum Toxin Type A:  Swelling, bruising, Headache, rash, itch, and very rarely flu like and adjacent muscle may be weakened for several weeks after the eyelid or an eyebrow. This could last 2-3 weeks.  *Please do not rub the injected area immediately after the tree.	r an injection, which may cause a te			
Risk and side effects of Dermal Fillers:  Redness, swelling, bruising, tenderness or itching sensation. Occasional cases of bumps and pimples. Very rare cases discolouration at the injection sites. In addition, rare cases of abscess (hard and swollen sore that may contain pus) and granuloma Necrosis is also a very rare but serious side effect that can occur post treatment. If you experience any discomfort as a result of treatment, you should notify Juvae immediately by calling 1300 255 913. If necessary, appropriate treatment may be prescribed.				
You should not apply make-up for 12 hours after the injection and should avoid prolonged exposure to sunlight, UV light, freezing temperatures or using saunas or Turkish baths for two weeks after the injection. If cheek augmentation treatment has taken place patients are recommended not to wear any restrictive facial attire, not to have face down massages or facial treatments such as laser for one month.				
I acknowledge that I have not had any permanent filler in the particle in the	oast 10 years or been treated by an u	unregisted	d person	
Please notify Juvae staff if you have untreated epilepsy, porph	yria, hypertrophic scarring, active rhe	eumatoid	arthritis.	
Patient's Signature:	Date:			

Medical Professional Signature:

# PERSONAL RECORD & PLAN



UPPER FACE REJUVENATION OPTIONS
MID FACE REJUVENATION OPTIONS
MID TACE REJOVENATION OF HONS
LOWER FACE REJUVENATION OPTIONS



	DATE/MONTH	REJUVENATION TREATMENT	INVESTMENT	NOTES
H				
H				
-				



Patient Information C	Contact Details			
Referring Clinic	Referring Doctor			
First name	Treating Nurse			
Surname	Expiry of Consent			
Date of birth	/			
Address No. & street				
Suburb				
State	Post code			
Mobile	Home			
Email	Work			
	s and information to you?  yes no			
	ur clinic?			
, , , , , , , , , , , , , , , , , , , ,				
Patient Information N	Nedical History			
Have you had Botulinum toxin t	type A or Dermal Filler Treatment before? If yes when/where/area/reaction	□ ves	∏nc	
		,		
Have you had Permanent fillers	s <mark>s</mark>	_	□no	
Are you prone to cold sores?		☐ yes	□nc	
Are you a smoker?		☐ yes	nc	
Have you had a Alcoholic drink today? If Yes How many			□ nc	
Do you have any allergies? If Yes please describe			□nc	
Are you allergic to any blood p	oroducts or local anaesthetic?	yes	nc	
Are you pregnant/breast Feedi	ing/ intending to become pregnant/IVF treatment? *	yes	nc	
Do you take herbal supplements/ blood thinning medication (fish oils, aspirin, NSAIDs, Heparin, Warfarin)?			□no	
	ry (including minimally invasive facial procedures (threading, implants) in the last	_ $\square$ yes	∏nc	
	sting or current medical conditions?	_	□nc	
Have you had any major dental work in the last 4 weeks?			□ nc	
Are you currently undergoing in	nvestigations for any health concerns by general practitioner?	yes	□nc	
	al Disorders or Neuromuscular Disease such as nia gravis, Eaton Lambert syndrome, muscular weaknesses?	☐ yes	□nc	
Are you planning to have any	waxing, laser treatment or Skin resurfacing to face area today?	☐ yes	□no	
	to any of the questions marked with * you will not receive treatment today.  edical condition ever changes in future please advise us prior to treatments			
I acknowledge that the i	nformation I have provided above is correct to the best of my know	ledge		
Patient's Signature:	Date			
i anem s signature	Date:			

# Prescription and Plan for injection of Botulinum Toxin Type A & Hyaluronic Acid Dermal Filler

Patient			DOB:			
Dr		Requesting Nurse:				
Product	Area to be treated	Dose	<u>Dose</u>	Frequency/Repeats	Тор ир	
Botulinum Toxin Type A	Crow's feet Frown Forehead Chin/Gummy Upper lip Brow lift Hyperhidrosis Masseters All of the above	Botox 10 - 40u 10 - 40u 10 - 40u 02 - 12u 02 - 12u 50 - 150u 20 - 60u	Dysport  10 - 90u  10 - 90u  10 - 90u  02 - 30u  02 - 30u  150 - 300u  50 - 90u	3-6 monthly 3-6 monthly 1.5-2 monthly 1.5-2 monthly 1.5-2 monthly 3-6 monthly 3-6 monthly	2-4 weeks	
Dermal Filler Hyaluronic Acid Dermal Filler Hyaluronic Acid	Lips N/Labials Forehead Frown/ brow Marionette Cheeks Hands Orbital Rim Nose Jaw All of the above	0.5 – 1mls 0.5 – 1mls 0.5 – 1mls 0.5 – 1mls 0.25 – 1mls 0.5 – 4mls 0.5 – 4mls 0.5 – 3mls 0.5 – 2mls 0.5 – 1mls 0.5 – 3mls	0.5 – 1mls 0.5 – 3mls 0.5 – 1mls 0.25 – 1mls 0.5 – 4mls 0.5 – 3mls 0.5 – 2mls 0.5 – 1mls 0.5 – 3mls	1-24 monthly	2-4 weeks As required	
Initial Treatment Plan <b>Date: Doctors Signature:</b>						
	Reviewed Treatment Plan Date: Doctors Signature:					
Notes regarding rev  Reviewed Treatment  Notes regarding rev				Signature:		
Reviewed Treatment	nt Plan Date:			Signature:		

# Informed Consent form for Botulinum Toxin Type A & Informed Consent for Hyaluronic Dermal Filler

It is important that you are informed about your skin condition and proposed treatment including the potential benefits and risks involved. This disclosure is not meant to scare or alarm you; it is simply an effort to better inform you so that you may give or withhold your consent to the treatment program.				
of(address)				
have requested that Juvae medical staff attempt to improve my facial expression lines with purific	d Botulinum toxin			
type A treatment. Botulinum toxin type A treatment has been used for more than a decade in ch	ildren and adults			
to treat therapeutic conditions such as involuntary facial muscle spasms and double vision due to imbalances. Injection of tiny amounts of Botulinum toxin type A treatment weakens the treated muscle spasms.	•			

prevent the formation of expression lines. Botulinum toxin type A treatment is included on the Australian Register of

The practice of medicine is not an exact science and no guarantees can be or have been made concerning expected results. I understand that several appointments maybe necessary to complete the treatment.

Therapeutic Goods (ARTG) for cosmetic use in frown lines, crow's feet and forehead lines.

I am aware that when small amounts of purified Botulinum toxin type A treatment are injected into a muscle it causes weakness in that muscle. This takes 4-7 days to take effect and usually lasts 3 - 4 months but can be for a longer or shorter period. I understand that the muscles injected will not function whilst the injection is effective (e.g.: I will not be able to frown if the muscles involved in frowning are injected) but that this will reverse itself after a period of months at which time re-treatment is appropriate.

I acknowledge that the expert advice given by the medical professional on the recommended dosage may vary from person to person, should I require any additional dosage of Botulinum Toxin post treatment an additional fee will be incurred.

Initial Here

I acknowledge that treatment to the forehead area will only last between 6-8 weeks and I will need to be retreated again, due to the low dosage required to treat the area.

**Risk and side effects:** Side effects and complications are usually minimal. It is administered via injection and with all treatments delivered this route slight swelling, and/or bruising may occur. Occasionally generalised side-effects can occur such as headache, rash, itch, and very rarely flu like symptoms and allergic reaction. An adjacent muscle may be weakened for several weeks after an injection, which may cause a temporary drooping of the eyelid or an eyebrow. This could last 2-3 weeks. I have been advised of the risks involved in such treatment, the expected benefits of such treatment, and alternative treatments, including no treatment at all.

\*Please **do not** rub the injected area immediately after the treatment. Please remain upright for 6 hours after the injection.

**Pregnancy and Neurological Disease:** I am not aware that I am pregnant and I do not have any neurological disease. Please notify your doctor if you have any allergies, autoimmune disease or are taking any medications or herbal supplements.

I agree that this constitutes full disclosure, and that it supersedes any previous verbal or written disclosures. I certify that I have read, and fully understand, the above paragraphs, and that I have had sufficient opportunity for discussion and to ask questions. I consent to this Botulinum Toxin Type A injection procedure today and for all subsequent treatments.

I have requested that Juvae medical staff attempt to improve my facial appearance with hyaluronic acid filler treatment. Hyaluronic Acid is a natural substance (a complex sugar) that stabilizes the skin structure, attracts and binds water, and contributes to the elastic properties of the skin that allow it to remain tight. Injections of Hyaluronic acid into the skin are thought to replenish its natural support structures damaged by aging. Dermal fillers are commonly used for filling in facial wrinkles and hollows and for lip augmentation.

Over time, Hyaluronic Acid injectable gel is gradually and naturally degraded in the human body. The effect of Hyaluronic Acid generally lasts for six months or longer depending on the area treated. Follow-up treatments are needed to maintain the effects of the Hyaluronic Acid.

Your doctor has prescribed Hyaluronic Acid injectable gel which may or may not contain a local anaesthetic (0.3% lidocaine). Lidocaine is added to the formulation to increase comfort during injection and treatment. Your doctor will inform you of which Hyaluronic Acid formulation is prescribed for your treatment. You should not apply make-up for 12 hours after the injection and should avoid prolonged exposure to sunlight, UV light, freezing temperatures or using saunas or Turkish baths for two weeks after the injection. If cheek augmentation treatment has taken place patients are recommended not to wear any restrictive headwear including swimming goggles, large sunglasses or motor bike helmets for one month post treatment. Clients are also recommended not to have any facedown massages or facial treatment that involves pressure or laser treatment to the area for one month post treatment.

Injections of Hyaluronic Acid may cause some of the risks listed below. Although the risk of developing a serious complication is small, your doctor will monitor you closely, and, should a complication occur, they will use their best medical judgment to do whatever is necessary to treat the problem. Risks associated with the use of Hyaluronic Acid treatment are redness, swelling, bruising, tenderness or itching sensation in the treated area. These common side effects typically resolve within a few days. Occasional cases of bumps and pimples, sometimes accompanied by redness, may occur a few days to a few weeks after the injection. These common side effects are temporary and generally disappear spontaneously in a few days. Very rare cases of reversible discolouration at the injection sites have also been described after Hyaluronic acid injections. In addition, rare cases of abscess (hard and swollen sore that may contain pus) and granuloma (small accumulation of tissue) have been reported. Necrosis is also a very rare but serious side effect that can occur post treatment. If you experience any discomfort as a result of treatment, you should notify your doctor immediately by calling 1300 255 913. If necessary, appropriate treatment may be prescribed.

\*\*Athletes should be aware that the product contains an ingredient that may produce a positive anti-doping test.

I acknowledge that I have not had any permanent filler in the past 10 years or been treated by unregistered person \_\_\_\_\_\_ Initial Here

If you have previously had permanent dermal filler implanted or been treated by an unregistered person you should notify your doctor prior to receiving treatment with Hyaluronic Acid injectable gel. The possibility of unknown risks exists. The safety of Hyaluronic Acid for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established and therefore should not be used under these circumstances. Please notify your doctor if you have any allergies (including hypersensitivity to Hyaluronic acid or lidocaine), untreated epilepsy, porphyria, hypertrophic scarring, active rheumatoid arthritis, an autoimmune disease, or are taking any medications or herbal supplements.

The practice of medicine is not an exact science and no guarantees can be or have been made concerning the expected results. I agree that this constitutes full disclosure, and that it supersedes any previous verbal or written disclosures. I certify that I have read, and fully understand, the above paragraphs, and that I have had sufficient opportunity for discussion and to ask questions. I consent to this Hyaluronic Acid injection and Botulinum Toxin procedure today and for all subsequent treatments as per the medical officer's recommendation.

Patient's Signature:	Da	te:
Doctor's Signature:	Da	te:

PLEASE TAKE THE TIME TO READ THIS CAREFULLY AND TO UNDERSTAND ANY ACCOMPANYING INFORMATION



WATCH

'What happens as we age and what is possible'

ON YOUTUBE





the experts in non-surgical solutions

Customised Juvae Beauty Plan

Date of Appointment \_\_\_\_\_ Time \_\_\_\_

Location \_

from here to here

1300 255 913

\*Juvae has a 24hr cancellation policy. If you miss/change/cancel your appointment in less than 24hrs you will forfeit your deposit.

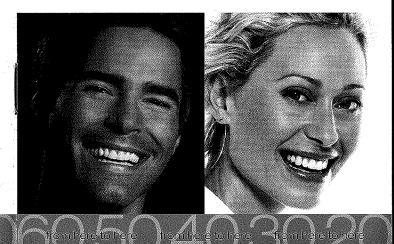


Our pursuit. Life's potential. $^{\text{\tiny TM}}$ 



# The total look





# A real approach to enhancement and rejuvenation

The face can be split into three distinct areas – the upper, mid and lower face. As we age, changes to each of these areas can occur at different rates in all of us. The key to retaining a fresh and natural look is to achieve balance and harmony across all three areas of the face.

In this brochure we'll look at the ageing process and some of the treatment options for each layer of the skin. Three treatment types provide results to restore and enhance your youthful features, especially when they are used in combination. These treatment types are:

- Sion treatments that correct texture and promer lation issues
- 2 JUVÉDERM® treatments that can enhance and replace facial volume
- BOTOX® treatments that can relax wrinkle-causing facial muscles

You have been treated with JUVÉDERM® and BOTOX® so we'll provide you with some information about how JUVÉDERM® and BOTOX® work and what is involved in the procedures. By combining the benefits of skin treatments with BOTOX® and JUVÉDERM® you can enhance and rejuvenate your facial appearance with natural-looking results. Used together, these treatments form Allergan's Natural Look Total Treatment\*. Talk to your clinician about your individual treatment plan.



#### **Understanding the ageing process**

The face is one of the first parts of the body to show signs of ageing. But don't worry – it's natural and it happens to all of us. Below is some information to help you understand the changes that occur over time with facial ageing.

#### Skin

Over time, the process of replacing old skin cells with new ones naturally slows down. Underneath the surface, the natural substances that provide the skin with support decrease over time. As does the activity of the sebaceous glands, which reduces the skin's ability to retain moisture and stay supple.

#### Volume

It's the presence of substances like sugar chain complexes and fat under the skin that gives the face youthful contours and volume. When we are young we have a defined jawline with smooth contours, and our cheeks, lips and upper face are full of volume. The overall shape and contour of the face however changes with age. This is because over time we gradually lose facial volume and, as our skin becomes thinner, the effects of gravity can become apparent.

#### Muscle

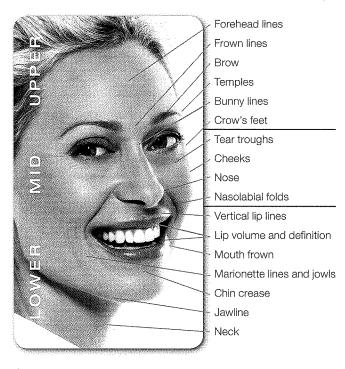
Over time our facial muscles decrease in strength and tone, reducing the support they provide to the soft tissue above them. When we're young our skin springs back easily into its initial position when we make facial expressions. However, as we age the repeated action of the facial muscles means that the 'dynamic' wrinkles (those formed during facial expressions) remain and form 'static' wrinkles (the wrinkles and folds that are present at rest).

#### Bone

The bones of our face form the 'foundation' over which the other layers sit. As we age, the structure of our bones change which can cause the facial foundation to become more or less prominent in relation to each other. This, in turn, can affect the look of fullness in these areas or can subtly alter the balance of our features.

# How do different areas of the face age?

Different areas of the face can age at different rates in each of us. Volume loss and repeated muscle action lead to facial ageing in these areas:



#### Skin tone and texture

The outer layer of our skin, that determines our complexion, is exposed to the elements everyday. If you have great skin now, the best thing you can do is guard it against the sun's harmful UV rays to keep your skin looking its best for longer.

Here are some skincare basics to keep you looking young and fresh:

- Protect against sun damage and premature ageing with a good sunscreen that contains zinc, and UVA and UVB filters
- Cleanse, moisturise and exfoliate daily to keep your skin smooth
- Drink plenty of water to keep your skin hydrated

#### Quick guide to skin treatments

#### Cosmeceuticals

Cosmeceuticals are topical skincare products that contain ingredients that help in the treatment of ageing and photo-damaged skin. Common ingredients in cosmeceuticals include: alpha and beta hydroxy acids (such as vitamin C, citric acid, glycolic acid and lactic acid), retinol (vitamin A), and antioxidants (vitamin C and E).

#### Resurfacing treatments

Chemical peels involve a solution of one or more exfoliating agents being applied to the skin to remove the rough upper layer of skin and stimulate the rejuvenation of new skin cells. They generally result in tighter, smoother skin that is relatively free of fine lines and discolouration such as age spots. Chemical peels can be light, medium or deep according to the depth that they penetrate the skin. Light and medium peels are used for superficial wrinkles and skin discolouration, whereas deep peels are used for conditions like severe acne.

**Dermabrasion** involves spraying fine crystal particles to exfoliate the surface of the skin. It has been shown to improve skin conditions such as uneven pigmentation, fine lines and texture irregularities.

Laser treatments work by emitting an intense beam of light that essentially 'resurfaces' the skin by removing superficial skin cells. There are many different types of lasers available that can reduce or remove hair growth, fine lines, scars, and even skin discolouration. Treatment may include the use of a local or topical anaesthetic cream. The recovery time depends on the type of laser and the area being treated.

Intense Pulse Light (IPL) differs from laser in that it delivers many different wavelengths of light to the skin and targets the lower layers of the skin (dermis) without affecting the upper layers (epidermis). IPL can be used to improve skin discolouration such as freckles, broken facial veins, rosacea as well as fine lines.

Resurfacing treatments can be repeated as necessary to achieve the desired results and your clinician will be able to advise you about which treatment is appropriate for you and your treatment plan.

# Fill me in on JUVÉDERM® hyaluronic acid injectable gel

JUVÉDERM® is a smooth injectable gel made from a natural complex sugar called hyaluronic acid. It is injected below the skin's surface to 'fill-in' wrinkles, 'plump-up' small areas such as the lips and 're-volumise' large areas like cheeks.

These treatments can help you regain naturally-defined contours and youthful facial curves with natural-looking and feeling results.

Faces change over time. Think back to your facial shape when you were younger, or look to your mother or father as to what you may look like in the the future. It is volume loss and soft tissue redistribution that influences much of this change.

#### Daughter



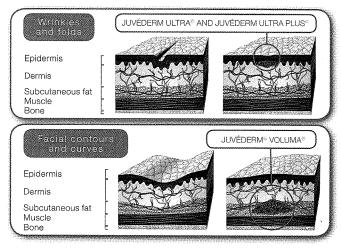
#### Mother

Representation of facial shape, contour and volume changes over time.

#### Frequently asked questions about JUVÉDERM®

#### What does JUVÉDERM® treatment involve?

JUVÉDERM® treatment is a non-surgical procedure administered through injection by a trained medical professional. The procedure usually takes between 15–30 minutes with results that can be seen immediately, and the majority of people resume their normal activities immediately after the procedure. For increased comfort during administration, some JUVÉDERM® products are specially formulated with a local anaesthetic.



#### How long does a JUVÉDERM® treatment last?

In its natural form, hyaluronic acid is a single chain sugar that is naturally broken down by the body within days. JUVÉDERM® is manufactured using proprietary HYLACROSS™ or VYCROSS™ technologies, which crosslink the molecules to slow their breakdown. This means results can last up to a year with JUVÉDERM Ultra® and JUVÉDERM Ultra® and up to 18 months with JUVÉDERM® VOLUMA®.

#### Are there any side effects?

Hyaluronic acid dermal fillers have been used for many years, and clinical trials have shown that JUVÉDERM® is well tolerated.

While you may experience no side effects at all, as with all medications, side effects can occur. Reported dermal filler side effects include injection site redness, pain, firmness, swelling, lumps and bumps, bruising, itching or discolouration. In the vast majority of cases, these effects are temporary and should resolve within a week. Ask your healthcare professional if you have any questions about side effects of treatment.

# Be refreshed and informed on BOTOX®

BOTOX® is a treatment option for those areas where repeated muscle movement is causing your 'dynamic' lines to turn into more permanent 'static' wrinkles.

Available in Australia and New Zealand for over 20 years, the natural purified protein in BOTOX® can target specific facial muscles involved in wrinkle formation to make a visible difference, leaving you with a refreshed, relaxed and natural look.

Glabellar frown lines are vertical lines that appear between your eyebrows when you frown.

FROWN LINES



AT REST



Crow's feet are lines that radiate from corners of our eyes. They're particularly pronounced when people squint or smile.

**CROW'S FEET** 



AT REST



Forehead lines are horizontal lines that form when you raise your eyebrows.

FOREHEAD LINES



AT REST



#### Frequently asked questions about BOTOX®

#### What does BOTOX® treatment involve?

BOTOX® is a natural, purified protein that relaxes wrinkle-causing muscles, creating a refreshed look. BOTOX® treatment is a non-surgical procedure whereby a small amount of BOTOX® is administered into selected facial muscles by a trained medical professional using a very fine needle.

Generally, BOTOX® treatment takes around 10 minutes. Discomfort is typically minimal and brief, and no anaesthetic is usually required. The injection may sting for a few seconds but there is usually no downtime needed and you are ready to get on with your day soon after treatment.

### When will I see results and how long will they last?

Generally, people start to see results within two days of their treatment and it takes about seven days for all results to be visible.

The effects of BOTOX® treatment usually last up to four months and gradually decrease over time. Regular BOTOX® treatments every four months may help improve the longevity of the treatment's effects.

#### Will facial expression be affected by BOTOX®?

BOTOX® is intended to enhance and refresh your look. Treatment will only relax muscles beneath the facial lines at the point of injection (so that other elements of facial expression remain active). If you choose not to have further BOTOX® treatments your muscles will eventually return to their former activity and your facial lines will gradually revert to their pre-treatment levels.

#### Are there any side effects?

In the vast majority of cases, any side effects are temporary, and are limited to where BOTOX® was injected. Possible side effects include: pain, burning or stinging; bruising, swelling or redness at the injection site; local muscle weakness including drooping eyelids or eyebrows; swollen eyelids and skin tightness; tingling sensations, itching or aching forehead; headaches, nausea and flu-like symptoms. Ask your healthcare professional if you have any questions about side effects of treatment.

JUVÉDERM® VOLUMA® injectable gels are Prescription Medicines which contain 20 mg/ ml. cross linked hyaluronic acid with (XC) or without lidocaine 3mg/ml. JUVÉDERM® VOLUMA® and JUVÉDERM® VOLUMA® XC are intended to restore volume of the face. The presence of lidocaine is meant to reduce the patient's pain during treatment. They should be administered only by trained medical professionals. Talk to your specialist about the benefits/risks of this procedure in appearance medicine. Caution: Should not be used in evelids, bads under the eyes, glabellar region or lips; not with another dermal filler; people with autoimmune disease; severe multiple allergies or anaphylactic shock; caution is required in patients having acute rheumatic fever with heart complications; history of streptococcal disease; undergoing anti-coagulant treatment; in combination with drugs that reduce or inhibit hepatic metabolism; hypersensitivity to hyaluronic acid; hypertrophic scarring; children; pregnancy; breast feeding and intravascular injection: areas of inflammation or infection avoid makeup for 12 hours after injection and prolonged exposure to sunlight/UV light/extreme temperatures for 2 weeks. JUVÉDERM® VOLUMA® XC should not be used in people with untreated epilepsy, hypersensitivity to lidocaine or amide-type local anaesthetics, or porphyria, in immediate association with laser treatment, deep chemical peel or dermabrasion; JUVÉDERM® VOLUMA® XC is not recommended for intramuscular injections. Caution with use in patients showing symptoms of cardiac conduction disorders; may produce positive results in athlete anti-doping tests. Possible side effects: Injection site inflammatory reactions (redness/swelling/itching/pain on pressure); induration or nodules; discolouration; weak filling effect; bruising; abscess formation, granuloma, necrosis in glabellar region, hypersensitivity. If you have any side effects or concerns speak to your doctor. You will need to pay for this medicine. Normal Doctors visit fees apply. Speak to your specialist about your own situation.

JUVÉDERM ULTRA® and JUVÉDERM ULTRA PLUS® with (XC) or without lidocaine injectable gels are Prescription Medicines containing 24 mg/mL cross linked hyaluronic acid. JUVÉDERM ULTRA® and JUVÉDERM ULTRA PLUS® are used for the filling of medium size and deep facial wrinkles by injection into the skin and for creating definition and volume in the lips. JUVÉDERM ULTRA® XC and JUVÉDERM ULTRA PLUS® XC are used for skin depression and restoration of volume. The presence of lidocaine is to reduce the patient's pain during treatment. They should be administered only by trained medical professionals. Talk to your specialist about the benefits/risks of this procedure in appearance medicine. Cautions: Should not be used in an area that has been treated with another dermal filler. People with autoimmune disease; or who are pregnant, breastfeeding, age under 18; or have an increased susceptibility to keloid formation and hypertrophic scarring. JUVÉDERM ULTRA® XC and JUVÉDERM ULTRA PLUS® XC should not be used for people suffering from untreated epilepsy, hypersensitivity to lidocaine or amide-type local anaesthetics, or porphyria; people having acute rheumatic fever with heart complications; history of streptococcal disease; undergoing anti-coagulant treatment; combination with drugs that reduce or inhibit hepatic metabolism; symptoms of cardiac conduction disorders; may produce positive results in athlete anti-doping tests. Possible Side Effects: Injection site inflammatory reactions (redness/swelling/tiching/pain on pressure); induration or nodules; discolouration; weak filling effect; bruising; abscess formation, granuloma, necrosis in glabellar region, hypersensitivity. If you have any side effects or concerns speak to your doctor. You will need to pay for this medicine. Normal Doctors visit fees apply. Speak to your specialist about your own situation.

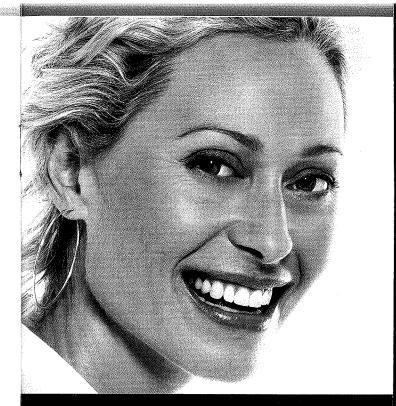
BOTOX° is a Prescription Medicine containing 100 units of botulinum toxin type A for injection. It is used for the treatment of frown lines, forehead lines and crow's feet. It should be administered only by trained medical professionals. Talk to your specialist about the benefits/risks of this procedure in appearance medicine. Cautions: People with defective neuro-muscular transmission disorders, infection at site of injection, glaucoma, pregnancy and lactation. Possible side effects include headaches, injection site pain/burning/stinging/bruising/swelling/ redness, local muscle weakness including drooping eyelids/eyebrows, eyelid swelling, skin tightness, tingling sensations, aching/tching forehead, nausea and flu-like symptoms. If you have any side effects or concerns speak to your doctor.

You will need to pay for this medicine. Normal Doctors visit fees apply. Note:  $BOTOX^{\circ}$  treatment lasts about four months and after this time further courses of treatment may be necessary. Speak to your specialist about your own situation.

BOTOX®, JUVÉDERM®, JUVÉDERM ULTRA®, JUVÉDERM ULTRA PLUS® and VOLUMA® are registered trademarks and Natural Look™, Our pursuit. Life's potential.™, HYLACROSS™ and VYCROSS™ are trademarks of Allergan, Inc. Allergan Australia Pty Ltd. ABN 85 000 612 831. 810 Pacific Highway Gordon NSW 2072. Allergan New Zealand Limited, PO Box 1873, Shortland Street, Auckland 1140. PP1742. ANZ/0034/2009a. ALL2081. 01/12. GHG.









AHPRA GPO Box 9958 Canberra, ACT, 2601

To Whom It May Concern:

RE: Juvae Submission to AHPRA regarding the administration of anti wrinkle injections and dermal fillers to clients by Juvae Registered nurses

and a Medical officer/Injector

for Juvae Pty Ltd.

The issue of regulation in cosmetic medicine is one that has been debated for quite some time. I do agree that there needs to be more regulation and I would put forth that a Juvae model of practice is one that provides that necessary system of checks and balances to ensure safe and consistent outcomes for the patient.

Current methods of practice employ nurse injectors with a doctor on site who does not see the patients face to face. In most cases the doctor will not even be aware of which patients are being treated. Other forms of practice include a nurse injecting 'in association with' or 'on behalf' of a doctor who is not on site, nor do they see the patients.

The Juvae model employs nurse or doctor injectors. In the clinic setting, the nurse assesses a patient and works with them to formulate a treatment plan. The doctor is involved via Skype and is able to speak with the patient face to face. In addition to answering any further questions the patient may have, the doctor is also able to identify any particular reasons the patient may not be suitable for the treatment. These reasons may not have been previously divulged to the nurse. The Skype session is also an opportunity for the nurse to express any concerns she may have.

Having seen the various models of practice in use, I can personally say that the Juvae model is the most thorough and ultimately provides the patient with the most reassurance.

In addition, Juvae's injectors are all put through a rigorous training course as well as regular fortnightly training sessions. This is by far the best ongoing training undertaken by any of the cosmetic injectors I have worked with. Ensuring the practices are up to date and that the most suitable products are used is a major component of cosmetic injecting that is overlooked by many practitioners.

As the company grows, they continue to refine their practices and I believe that the guidelines they have in place provide the greatest safety and security for their medical staff, nurses, and the patients. I would be more than willing to discuss any issues further if necessary.

Sincerely,



29th April 2015

AHPRA GPO Box 9958 Canberra, ACT, 2601

To Whom It May Concern:

## RE: Juvae Submission to AHPRA regarding the administration of anti wrinkle injections and dermal fillers to clients by Juvae Registered nurses

My name is I am currently employed by Juvae as a Registered Nurse. I have been a Registered Nurse for 13 years. I have been employed by Juvae since October 2014. Prior to this I was a clinical nurse specialist in the field of mental health. I have also completed a Graduate Certificate in Cosmetic Nursing through the Australasian Academy of Cosmetic and Dermal Sciences in May 2014. This course covered cosmetic injectables and was provided with practical training via a pharmaceutical company.

During my time of seeking employment in the field of cosmetic injectables my main precedence was working for a company that ensured that patient safety was a main priority, that I would receive comprehensive and adequate training and also continue with any professional development. When I commenced employment with Juvae I was satisfied and confident with Juvae's ethics and professional conduct to deliver the highest standard of treatment to clients whilst adhering to patient safety. When I started with Juvae I underwent an intensive period of training. This was both theory and practical based whilst having a high level of support from professionals in the field. Juvae provided a comprehensive training and ensured competency in delivering a professional service to clients receiving cosmetic injectables.

Along with the initial training with Juvae, the injectors, which consist of registered nurses and doctors, receive practical training every two weeks to ensure best practice and development of skills. This training also gives the opportunity to discuss any complex cases, patient safety, the latest research and new treatments and techniques.

Juvae have ensured strict protocol and procedures for injectors to adhere to when delivering treatment. This consists of skyping with a doctor prior to seeing any clients for the day to ensure we have an emergency pack with us at all times and to record our stock for the day. All clients seeking treatment are given a thorough and detailed informed consent that also includes and medical history. During the consultation process this consent form is once again repeated to the client and a thorough explanation of any risks and side effects are discussed with the client along with any medical history and possible contraindications. A complimentary facial assessment is provided and during this assessment the client is educated on the aging process. A discussion on what the clients concerns are is undertaken and which treatment options are most appropriate. If the client wishes to go ahead with treatment, they are required

to consult with one of our doctors. During this process a videoconference is conducted where by the doctor sights the client and goes through the medical history, the procedure, the risks and side effects. This process allows the client to have a discussion with the doctor and ask any questions that they may have. If the client is happy to receive treatment and the doctor is satisfied that there is no contraindications then treatment can go ahead. Due to injectables being a S4 medication the doctor will remain on video conferencing and any medication is drawn up in sight of the doctor and all appropriate dosages, batch numbers and expiry dates are recorded for the client records. Treatment is then commenced in an aseptic technique. Thorough care is taken during procedure for any potential or possible complications. The client is given thorough post care procedures verbally and also are provided with written post care instructions. On these post care instructions there is a phone number provided that the client is able to call 24 hours 7 days a week in case of any questions that they may have post treatment. All clients are encouraged to call this if they have any queries. Appointments are made at this time to be able to follow up the client after the procedure. All procedures are recorded both from the injector and the doctor on the client's records. This protocol is strictly adhered to for all clients that seek treatment through Juvae. At the end of the clinic a stock is then counted with the injector and the doctor via video conferencing to ensure no discrepancies.

During my time with Juvae I have received many compliments and comments from clients that I have consulted, treated and followed up at the professionalism and the thoroughness of the process from beginning to end. This provides me with confidence and pride when delivering services to clients and reinforces with me that that the strictest protocols are in place to deliver treatment around patient safety and satisfaction within regulation and evidence based practice.

Sincerely,

27<sup>th</sup> April 2015

AHPRA GPO Box 9958 Canberra, ACT, 2601

To Whom It May Concern:

# RE: Juvae Submission to AHPRA regarding the administration of anti wrinkle injections and dermal fillers to clients by Juvae Registered nurses

To whomever it may concern,

I refer to the letter from AHPRA requesting a submission in regards to best practice for cosmetic injectable service.

I am writing to you from the point of view of a cosmetic medical officer. I am currently appointed by Juvae Pty Ltd to fulfil the role of a supervising doctor for their cosmetic nurses. My position involves consulting all patients prior to any cosmetic treatments, via real-time video link. A typical consultation involves me taking a medical history, assessing the patient, answering any questions, discussing any concerns and ensuring that informed consent has been obtained. It is also my responsibility to keep a continuously updated record of S4 medication used i.e. Botulinum toxin and Hyaluronic acid fillers.

I would first like to stress that as a medical doctor I greatly respect my hypocrite oath, "first do no harm". Therefore before working with Juvae, I had to satisfy myself that they are a company that practices ethically, safely and within the law. From my experience with Juvae thus far, I believe that they have come up with an excellent best practice model that enables nurses to treat patients with injectable cosmetic products without compromising patient safety. Firstly, their nurses undergo a rigorous assessment and training program prior to commencement. I can be very confident that when I prescribe cosmetic treatments for patients, that they are performed by highly competent cosmetic nurses. Secondly, there is always a registered doctor available for consultation in the event of an emergency. It is very uncommon to see any major complication from injectable cosmetic treatments but when they do occur, a doctor is just a call away. Thirdly, it is mandatory that all nurses carry an "emergency kit". The policy at Juvae is that nurses are not permitted to inject unless they have a complete kit on them. The kit includes items required for management of anaphylaxis and vascular occlusion.

There is no doubt that there are many companies, nurses and doctors that are not complying with guidelines and code of conduct set out by AHPRA. It is definitely a field that requires further attention and regulation. It is also my belief that a high level of patient safety can be assured if organisations adopt a similar set of policy and procedures as that used by Juvae.

Should you require any further information please do not hesitate to contact me

Yours sincerely,

27th April 2015

AHPRA GPO Box 9958 Canberra, ACT, 2601

To Whom It May Concern:

RE: Juvae Submission to AHPRA regarding the administration of anti wrinkle injections and dermal fillers to clients by Juvae Registered nurses

My name is am a Registered Nurse injector with Juvae and have been a Registered Nurse since 2012. As a newly employed cometic injector I have recently completed my intensive 'boot camp' education. During this time I was mentored by not only 2 pharmaceutical companies but also experienced nurses and doctors to ensure that the nurses are both competent and safe injectors. Juvae as a company are very patient focused, which being a nurse is also my focus. They maintain high standards of professionalism, clinical knowledge, patient care and patient satisfaction. The ongoing support and education is outstanding, I can honestly say I have more support and ongoing facilitated learning in this role than I did as a new graduate nurse employed at the Royal Brisbane and Women's Hospital. My profession is not only my livelihood but it is also my passion, I therefore hold my registration of the upmost highest regard and would never practice in a way as to jeopardise my career or the safety and care of my patients. After doing my research into Juvae before accepting a position within the company and now after attending their head office for training and being lucky enough to attend a one on one clinical session with a world renowned cosmetic doctor and injector, I am very confident in the company and its practices. Each patient receives individualised care from well educated, competent and safe nurse injectors who with the doctor tailor treatment to suit each patient. Both the nurse and the medical doctor go through a detailed medical history and consultation process, the nurse in the clinic and the doctor via skype. The doctor has a one on one consultation with every patient and each patient is well informed and educated about the procedure they will receive and post care instructions. The nurses of Juvae take these procedures very seriously in order to ensure that we are performing within best. practice.

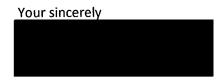
20<sup>th</sup> April 2015

AHPRA GPO Box 9958 Canberra, ACT, 2601

To Whom It May Concern:

## RE: Juvae Submission to AHPRA regarding the administration of anti wrinkle injections and dermal fillers to clients by Juvae Registered nurses

I am a registered nurse who has been working Hi my name is for a non surgical solutions company (Juvae) for the past 4 years. Prior to being employed with Juvae, I work with a cosmetic Dr who had hired me as a cosmetic injector. During the time I worked with this Dr I received minimal amount of theory and practical training in cosmetic injectables. My consultations and treatment where not up to scratch. I had struggled a lot during my facial consults and treatments that I provided. Until I was employed by Juvae. Since I have been working for Juvae the way I perform my facial consults and treatments are extremely through and I have noticed that by having satisfied patients it has made it possible for me to have a great amount of followings. The trainings that have been offered by juvae are secound to non. When I started with juvae both nurses and doctors had ongoing fortnightly training, case reviews and extremely thorough consent process. Prior to treatment of any patients all nurses at Juvae must Skype the doctor on call, the consent and treatment plan is again reviewed face to face via Skype. This process in place makes me feel very comfortable knowing that during my decision making and treatment planing the Dr is with me and my patient step by step. Juvae has chosen me on a number of occasions to participate in private Masterclass training sessions with world renowned Plastic Surgeons to further my specialised techniques. I am proud to say I couldn't be happier to work for such an outstanding company as a cosmetic Registered Nurse.



AHPRA GPO Box 9958 Canberra ACT 2601

To Whom it may concern,

Re: Juvae submission to AHPRA regarding the Administration of Anti-wrinkle Injections and Dermal Fillers to clients by the Juvae Registered Nurses.

I refer to the letter from AHPRA requesting a submission and on behalf of Juvae PTY LTD I will address your concerns below.

My name is and have been practicing as a Registered Nurse (RN) for the past fifteen years. I have been employed by Juvae since its conception and have undergone intense comprehensive studies pertaining to cosmetic injectables. My previous nursing experience was in Tertiary level Intensive Care.

In the last 6 years, Juvae has successfully treated clients for cosmetic needs without any serious adverse reactions. Juvae Consulting and Treatment Processes for non-surgical cosmetic procedure is to a high standard where focus is on patient safety first and cosmetic outcome second. This is achieved with both the cosmetic expertise of a Medical Officer and a Registered Nurse. Juvae believes best practice is achieved with a three party involvement structure: the Patient, the Cosmetic Medical Officer and Cosmetic Registered Nurse each and every time a client presents themselves to Juvae for treatment.

The Juvae process has seen that patients that present with symptoms of ageing have been able to have their cosmetic treatment done in a professional and safe setting. Juvae staff ensures that all legislative requirements are met and are adhered to at all times. We have structured procedures for the treatment, the post care and for complaints handling should they arise.

Juvae does not compromise on compliance or best practice - this is achieved by the following method of treatment delivery.

- 1. Live Video, face to face consultation where a cosmetically trained Medical Practitioner comprehensively covers the following with every patient:
  - Patient Medical History
  - Patient assessment
  - Patient treatment plan
  - Patient dosage
  - Patient's consent
  - Medication risk and side effects explained to the patient
  - Patients post care instructions
  - Any questions which the patient may have
  - Instructions to the Cosmetic Registered Nurse

- 2. The role of the cosmetic Registered Nurse at Juvae is to cover on the following with every patient:
  - Patient's Medical History
  - Patients consent signed
  - Patient's treatment plan, product and dosage with the patient and Medical Practitioner discussed and understood.
  - Patient's treatment
  - Post care instructions provided
  - Follow up booked in

Juvae registered Nurses undergo an intensive training program at the commencement of employment. This ensures all Registered Nurses have a complete and thorough knowledge on facial anatomy and furthermore a comprehensive understanding of high risk areas and how to manage adverse reactions. Juvae Cosmetic Medical Officers oversee all treatment plans and dosage to ensure no registered Nurse is operating outside their scope of practice and capacity.

All Juvae nursing staff are assessed and signed off prior to the treatment of any patients. They are assessed on all areas of the facial anatomy and placement of the product. All Juvae injecting staff have an individual tailored professional development plan and documented mandatory training is organised once a month to reassess and develop nurse's skills and competency. This ensures that patient safety and patient outcomes are delivered and achieved continuously.

Juvae also have the following process to ensure that patient outcome is to the highest of standards and ensure that processes are continuously developed to ensure that Juvae achieves the best outcome for their patients:

- Complaints register Overseen by Nurse Manager and Cosmetic Medical Officer
- Adverse reactions register Over seen by Nurse Manager and Cosmetic Medical Officer
- Juvae Cosmetic Medical Officer is available immediately for any complications
- No medication is sold to the registered nurses
- All S4 Medication is the Medical Officer's sole responsibility and is monitored with every patient and our Drug Book is updated with each patient after consent.
- All Registered Nurses undergo CPR training annually
- Juvae ensures that every patient is consulted with a Medical officer who is responsible and
  determines the dosage and treatment plan on every occasion. The Medical Officer is able to
  advise if the medication dosage should be amended to meet the symptoms that the patient
  displays.
- Fully contained medical kit for any emergencies that may arise.

Juvae believes that our practice ensures that patients are treated safely. Patients are informed of the treatment including its risks, are involved in their treatment decisions and are under no obligation to be treated hence specific consultation appointments must be done prior to the activation of any treatment plan. This gives the patient time to process the information, do further research which we advise and assess the financial aspect associated with the treatment.

The Juvae standard of care requires Cosmetic Registerd Nurse to utilize best practices at all times. Legal standards are set at an acceptable minimum; however Juvae prides itself on higher standards and continuously strives for optimum care. The goal of evidence-based medicine, for example, is optimum treatment of every patient.

One of the major points in the development of evidence-based medicine is the recognition that wide variations in medical practice exist. Evidence-based medicine brings together clinical expertise and best current research evidence which we assess and implement accordingly.

The standard of care is broad and vague. One cosmetic practice method of therapy may be considered suspect or even negligent by another cosmetic practice. Currently some practices have no Medical Officers consulting the client at all (yet a Medical Officer is on site) in other cases Medical Officers have lent out their prescriber number to nurses to use which also is not within the scope of the legislation.

Juvae patient flow is high and to date, patient outcomes are very positive and with minimal patient dissatisfaction due to our diligent best practice process. Evident through our operation procedure and satisfied patient outcome, we believe that the Juvae best practice model for non-surgical procedures is the benchmark in non-surgical solutions. Juvae's conservative approach ensures that procedures and processes are in place to safeguard the patient at all times. The Juvae best practice model has been unachievable for many practices due to the high costs associated with the continuous monitoring and diligent processes from the Medical Officer. We agree that a high benchmark be set to make sure that all treatment are safe and made by qualified trained Cosmetic Injectors, ensuring that patients outcomes are always positive.

Should you require any further information please do not hesitate to contact me Additionally we are willing to provide more details on our best practice model to assist with standardising safe practices for other cosmetic injectable businesses.

Sincerely,

24 April 2015

30<sup>th</sup> April 2015

AHPRA GPO Box 9958 Canberra, ACT, 2601

To Whom It May Concern:

RE: Juvae Submission to AHPRA regarding the administration of anti wrinkle injections and dermal fillers to clients by Juvae Registered nurses

My name is cosmetic medical officer working for Juvae for the past year. When applying to work as a cosmetic injector and officer I was sure to do my research about the company Juvae before accepting to work them. As a doctor, patient care and safety is my primary concern. I was well aware of patients receiving cosmetic injectables by both doctors and nurses who were not adequately trained, there is no shortage of this in the media. During my interview process at Juvae my main concerns were whether there was protocol in place for both training staff at initial employment, whether ongoing training was in place and whether their was adequate supervision. Juvae completely exceeded my expectations. They have very tight protocols in place for the administration of cosmetic injectables. Starting from the intense training of all their staff both nurses and doctors, ongoing fortnightly training, case review of challenging cases and a very detailed consent process. All nurses must Skype the on call doctor prior to treatment where by as the doctor the consent and treatment plan is again reviewed face to face via Skype. As the doctor I am able to make a safe decision with regard to prescribing the use of muscle relaxants or fillers to patients as I have both a highly trained nurse and patient available to me to answer my questions via Skype. I would never work for a company that did not value the patient first and their safety. At Juvae their prime focus is the patient. This is why I chose to work with them. Their values were the same as mine. I can make safe decisions and accurate decisions regarding prescribing cosmetics for nurse use on patients whilst working with Juvae. By having a doctor on site this does not necessarily mean the doctor will see all patients. At Juvae, the protocol is that doctors do see patients even though this is done via videoconferencing.

When I completed my initial training with the cosmetic pharmaceutical companies on administration of both muscle relaxants and fillers they were happy for me to start treatment on patients with nil further training even though I did not believe it was adequate enough. When I started with Juvae they provided further training to ensure the utmost quality of service was provided to their clients.







#### Post care instructions for Botulinum Toxin Type A

Do NOT rub or touch the treated area until the next morning. This includes not having any facial treatments, laser or massage. This is to help avoid any complications.

It is recommended you do NOT lie down for the next 4-6 hours as you many inadvertently rub the treated areas. For the same reason you should not do strenuous exercise for the day of treatment.

Also, avoid any exposure to any heat treatments such as sauna, hot tub or tanning for 48 hours as it will make your treatment less effective.

Paracetamol is recommended for any headaches or pain. Try to avoid medicines such as ibuprofen (Nurofen) or diclofenac (Voltaren) for the next 24 hours.

There is a small risk of bruising. If this occurs do not worry, it will only be temporary, is generally minor and can easily be covered up with makeup. Arnica tablets or hirudoid cream helps reduce bruising time if it is of concern.

Your treatment will take 4-7 days to start working. It may take 2 full weeks to see the final result. *If, after 2 weeks, you feel that you still have more muscle movement than you would like, then this can be adjusted at your post injection assessment.* 

#### Post care instructions for Dermal Fillers

Do NOT rub or touch the treated area until the next morning.

Do NOT consume alcohol for 24 hours after treatment.

Try to avoid lying down or strenuous exercise for 6 hours after treatment.

It is recommended to avoid extended exposure to sun or UV light and extended exposure to extreme hot or cold temperatures including hot drinks (if your lips have been treated) 2 weeks.

It is recommended not to apply make up to the treatment area for 12 hours after the injection.

There will be some swelling and bruising, however do not worry as it will only be temporary and can easily be covered up with makeup (after 12 hours). Arnica tablets or hirudoid cream can help if it is of major concern.

You may feel lumps for up to 2 weeks after treatment, as your body adjusts to the new volume. You may after 48 hours, massage these out gently. If you can see any lumps please let the staff at Juvae know. If you feel any pain, feel hot, become a mottled white colour at the sight of the injection, or have a large bruise you need to contact 1300 255 913 immediately and get the emergency number.

If you have any concerns please contact Juvae Staff on 1300 255 913.





#### PROTOCOL FOR HYALASE INJECTION

Hyalase (Aventis Pharma) is a hyaluronidase that has been use widely in surgery as an aid in dispersion of local anaesthetic. It helps with hydro-dissection.

It works by depolymerizing the HA into smaller polysaccharide chains. It is extremely effective in removing excess exogeneous HA based fillers.

#### **Dilution**

Dilute the ampoule (1500 IU) with 5ml of sterile water or Normal Saline. Final concentration 300 units per ml.

#### **Dose**

Normally use 30 units (0.1ml) to 45 units (0.15ml) per site to. Aim to be conservative for it can remove all the fillers if use too much.

#### <u>Injection technique</u>

Hyalase works best if it is placed directly in contact with the offending portion of HA fillers. IE. Be very précised. In the lips I would recommend multiple puncture sites of 0.025 if we are trying to reduce the overall fullness rather than one discrete area.

Once injected, gentle massage the area to disperse the hyalase.

In localised problem, you can see and fell an almost instantaneous improvement once in the right spot



Date: \_\_\_\_\_

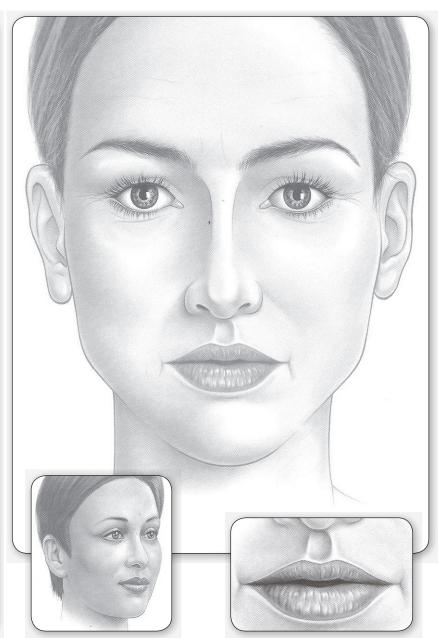
Patient Information Contact Details			
First name  Surname	Treating Nurse  Expiry of Consent		
Date of birth/	EXPITY OF CONSCIEN		
Patient Information Medical History			
Have you had Botulinum toxin type A or Derma Filler Treatment Do you have any allergies including blood products or local ar If yes please describe	nesthetic?	□ yes	□ no
Are you pregnant/breast feeding/ intending to become pregn Do you take herbal supplements/ blood thinning medication (a If yes please describe	aspirin, NSAIDs, Heparin, Warfarin)?	□ yes	no no
Are you currently suffering from any sinus infections?  If yes please describe		yes	no
Have you had facial surgery or recent dental procedures?  If yes please describe		yes	□no
Are you planning to have any waxing, laser treatment or skin reface area today?	esurfacing treatments to your	yes	no
Do you have any other pre-existing or current medical conditions of the pre-existing or current		yes	no
Do you suffer from *Neurological Disorders or Neuromuscular D disease, Myasthenia gravis, Eaton Lambert syndrome, muscula		yes	□no
*If you have answered YES to any of the questions marked with	* you will not receive treatment toda	ay.	
Risk and side effects Botulinum Toxin Type A:  Swelling, bruising, Headache, rash, itch, and very rarely flu like:  An adjacent muscle may be weakened for several weeks after the eyelid or an eyebrow. This could last 2-3 weeks.  *Please do not rub the injected area immediately after the tree.	r an injection, which may cause a te		
Risk and side effects of Dermal Fillers:  Redness, swelling, bruising, tenderness or itching sensation. Occ discolouration at the injection sites. In addition, rare cases of cand granuloma Necrosis is also a very rare but serious side effecting any discomfort as a result of treatment, you should notify Juvae appropriate treatment may be prescribed.	abscess (hard and swollen sore that not that can occur post treatment. If	nay conto you expe	ain pus) rience
You should not apply make-up for 12 hours after the injection of freezing temperatures or using saunas or Turkish baths for two whas taken place patients are recommended not to wear any refacial treatments such as laser for one month.	veeks after the injection. If cheek au	gmentati	on treatment
I acknowledge that I have not had any permanent filler in the particular in the part	past 10 years or been treated by an u	unregisted	d person
Please notify Juvae staff if you have untreated epilepsy, porph	yria, hypertrophic scarring, active rhe	eumatoid	arthritis.
Patient's Signature:	Date:		

Medical Professional Signature:

#### PERSONAL RECORD & PLAN



UPPER FACE REJUVENATION OPTIONS
MID FACE REJUVENATION OPTIONS
MID TACE REJOVENATION OF HONS
LOWER FACE REJUVENATION OPTIONS



	DATE/MONTH	REJUVENATION TREATMENT	INVESTMENT	NOTES
H				
H				
-				



#### Consent to Hyaluronidase (Hyalase®)

lof	address		have
requested that Juvae medical staff	use Hyaluronidase	e (Hyalase <sup>®</sup> ) to co	ompletely or partially
remove Hyaluronic acid dermal fille	er I have previously	y had injected. I	am aware this often
requires more than one treatment	, and cannot be	undertaken less	than 4 weeks after
reatment with dermal filler. I un	derstand I will be	required to ret	urn for a follow-up
appointment in 2 weeks.			

Hyaluronidase is an enzyme that breaks down Hyaluronic acid, such as that found in dermal fillers including Restylane and Juverderm. I understand that injection of Hyaluronidase (Hyalase®) will remove dermal filler from the area being treated. I understand that the purpose of this procedure is to improve the appearance of my facial contours by partially or completely dissolving dermal filler, and that the results of this procedure may be variable. As such, Juvae cannot guarantee that perfect results will be achievable with one, or more than one, treatment.

Hyaluronidase is used for other indications outside cosmetic medicine, including subcutaneous infusion of fluids, pain relief in child birth and prevention of post-partum haemorrhage.

I understand that Hyaluronidase (Hyalase<sup>®</sup>) cannot be used at sites of any bites or stings, or in any areas of infection or malignancy. I confirm that I do not have a known allergy or hypersensitivity to Hyaluronidase (Hyalase<sup>®</sup>), or to egg or egg products, or to animal products.

I am aware of the risks and possible side effects of Hyaluronidase (Hyalase<sup>®</sup>) as listed here:

- Allergic or hypersensitivity reaction including rash, difficulty breathing, facial swelling, swelling of tongue or throat (occurs rarely)
- Pain, itching, redness or swelling at the site of injection
- Bleeding and/or bruising at the site of injection
- Infection at the site of injection
- Complete removal of dermal filler after attempted partial removal
- Need for repeated treatments to achieve desired result

I am aware that Hyaluronidase (Hyalase<sup>®</sup>) cannot be used in pregnancy or breastfeeding. I have told Juvae medical staff if I am taking any of the following medications: Frusemide, Phenytoin, Heparin, Adrenaline, or any of the Benzodiazepines (such as Valium).

I agree to notify Juvae medical staff and seek immediate medical help if I develop any of the following symptoms after treatment:

- Redness or swelling at the site of injection
- Difficulty breathing, or swelling of the lips/tongue
- Chills, nausea, vomiting, dizziness, palpitations.

I agree that this constitutes full disclosure, and that it supersedes any previous verbal or written disclosures. I certify that I have read and fully understand the above paragraphs and that I have had sufficient opportunity to ask questions. I consent to treatment with Hyaluronidase (Hyalase®) today and to all future treatments.

I am aware the cost of this procedure,	per area and per treatment, is \$300.

Patient signature	Date
Doctor Signature	Date

# Medical Officers Hylase Patient Consent and Script Form

Entered into SS Script emailed to injector Uploaded to icloud



**Patient Medical History & Contact Details** Referring Doctor Referring Clinic \_\_\_\_\_Treating Nurse First name Expiry of Consent Surname Date of birth \_\_/\_\_\_/\_\_\_ Have you had Botulinum toxin type A or Dermal Filler Treatment before? If yes when/where/area/reaction Have you had Permanent fillers? yes no Are you allergic to any animal products such as eggs ahnd seafood? yes no Are you prone to cold sores? ☐ yes ☐ no Are you a smoker? yes no Have you had a Alcoholic drink today? If Yes\_\_\_\_\_ How many ☐ yes no Do you have any allergies? If Yes please describe \_\_\_\_ yes no Are you allergic to any blood products or local anaesthetic? \_\_\_\_\_ ☐ yes no Are you pregnant/breast Feeding/ intending to become pregnant/IVF treatment? \* ☐ yes no Do you take herbal supplements/ blood thinning medication (fish oils, aspirin, NSAIDs, Heparin, Warfarin)? ☐ yes no Have you had any facial surgery (including minimally invasive facial procedures (threading, implants) in the last ☐ yes Do you have any other pre-existing or current medical conditions? \_ ∏ yes ∏no Do you suffer from \*Neurological Disorders or Neuromuscular Disease such as Autoimmune disease, Myasthenia gravis, Eaton Lambert syndrome, muscular weaknesses? yes no \_\_\_\_ Area Treated \_\_\_ Dose \_\_\_ Initial Treatment Plan **Date**: Doctors Signature: \_\_\_ Doctors Signature: Reviewed Treatment Plan Date: \_\_ Notes regarding review: \_\_\_ Skype call made to \_

# JUV'ae





