



7<sup>th</sup> July 2015

Mr Peter Colgan  
The Manager  
National Uniformity and Regulatory Systems  
ARPANSA  
P O Box 655  
MIRANDA NSW 1490

Dear Mr Colgan

**RESPONSE TO CONSULTATION DRAFT: REGULATORY IMPACT STATEMENT –  
INTENSE PULSED LIGHT SOURCES (IPLs) AND LASERS FOR COSMETIC OR BEAUTY  
THERAPY**

The Cosmetic Physicians College of Australasia Ltd (CPCA) is pleased to respond to the ARPANSA regarding the Regulatory Impact Statement: Intense Pulsed Light Sources (IPLs) and Lasers in Cosmetic or Beauty Therapy – Consultation Draft.

***About the CPCA***

The CPCA will represent the largest group of doctors in Australia with a special interest in minimally-invasive cosmetic medicine. One of the CPCA's primary endeavours is to safeguard the public by ensuring regulations are adhered to and standards are upheld in this evolving area of medicine.

The CPCA is a new organisation derived from the Cosmetic Physicians Society Inc. Its aims are similar to those of the Society but with a stronger emphasis on education, training and standards. The CPCA will answer, where possible, the questions as posed through the RIS and expand where it feels that ARPANSA should focus its efforts.

***Responses to Consultation Questions***

***Stakeholders are invited to provide feedback on whether the nature and magnitude of the problem is accurate. If not, please provide additional details to add to or correct the data in this section.***

The CPCA feels that the magnitude of the problem is probably significantly under-represented. While it has no specific figures for this, the CPCA feels that there is a large number of harmed persons who will self-treat or seek medical attention without that being reported to bodies which will collate the data or provide it to an organisation such as ARPANSA.

***Stakeholders are invited to provide their views on the significance of the problem in jurisdictions that do not regulate IPLs and lasers for cosmetic or beauty therapy.***

The CPCA believes the problem is certainly greater in jurisdictions where there is no regulation. It is always of concern, however, where partial regulation occurs. In Qld, where Class 4 lasers are regulated, there is a noticeable problem with IPLs being sold to those who will not qualify for licences and also less-scrupulous distributors have mislabelled lasers as Class 3, when they are actually Class 4, to avoid the need for licensing. This puts potentially-harmful equipment in the hands of those who would otherwise be excluded from operating such devices.

The CPCA would therefore encourage ARPANSA to ensure that all lasers and IPLs which are used for cosmetic and beauty therapy treatments are included in these regulations, regardless of classification and that new forms of energy-based devices are also monitored to see whether they also should be included in such regulations. We note a recent release by the Queensland Minister for Health advising of a crackdown on premises using Class 4 lasers which have been incorrectly labelled Class 3 for tattoo removal.

***Stakeholders are invited to comment on the options described and suggest other feasible options to achieve the objective of reducing the number of serious injuries from the commercial use of IPLs and lasers.***

The CPCA has a strong preference for Option 3 and does not feel the other options are feasible in terms of reducing injuries. Further comments will be included with the following answers.

***Stakeholders are invited to provide feedback on the assumptions used to estimate the costs of consumer awareness campaigns, operator training and the production of guidance documents and the benefits of Option 1 (educational awareness).***

Consumer education information is often found and noted by those who are, by nature, more cautious or who would gather information on the best procedures and practitioners anyway. Those who are more impulsive often make decisions based on convenience, cost, after seeing a glossy advertisement with inflated claims, or on a whim, with little thought for safety and would therefore benefit little, if at all, from such educational efforts.

The cost of any such campaign would be immense. The campaign would need to be ongoing and always changed and updated according to the advances in available technology.

***Stakeholders are asked to provide feedback on the assumptions used to estimate the costs and benefits of Option 2 (self-regulation through a voluntary accreditation scheme).***

The CPCA feels that those who are likely to be bound by industry self-regulation are those who are already using best-practice methods. It is likely to not encompass those who are most at fault. Those who currently use low-cost operations would continue to do so and self-regulation would only increase the costs (and therefore the cost to the consumer) of those already producing safer results. This would therefore drive the cost-conscious consumer towards the lower-quality operators and not produce the hoped-for reduction in injuries.

***Stakeholders are asked to provide feedback on the percentage of the industry that has adequate qualifications and the assumptions used to calculate this compliance cost.***

The CPCA does not feel that it has the knowledge to accurately answer this. Doctors should have the ability to diagnose the conditions to be treated whereas this is not the case with non-doctor operators. Those who are already licensed in those jurisdictions that have licensing should have the knowledge and experience to operate the equipment for which they are licensed, although non-doctors may still not have the ability to diagnose the conditions which they treat.

The CPCA believes that there are a lot of operators in jurisdictions which have no regulation that would be considered unqualified and there would still be a lot of operators in, say, Queensland, that use IPL or lasers which have been “classified” as less than Class 4 that would also be considered unqualified. We do not have figures for this statement.

***Stakeholders are invited to provide feedback on the assumptions used to estimate the costs and benefits of Option 3 (licensing of operators).***

The CPCA believes that this is the only option which would significantly impact on the rate of injuries. It would also allow records to be kept of numbers, locations and identities of operators throughout the country. Also, if all operators need licences to use all lasers and IPLs for cosmetic and beauty therapy treatments, it would reduce the incentive for distributors to fly beneath the radar and sell mislabelled lasers to operators who are unable or unwilling to obtain such licences. Uniform regulation throughout the country would also make it easier for distributors to deal with all their customers in the same fashion rather than needing different processes in different states.

It would be expected that all courses, whether provided through internal medical college-based fellowship training, external medical education or via any industry groups would meet or exceed an agreed standard and be applied equally to all medical practitioners irrespective of other qualifications.

***Stakeholders are invited to comment on the expected competition effects, in particular whether Option 3 would result in significant restrictions to competition. Where possible, stakeholders are requested to provide data to support their views.***

It is likely that some non-medical operators who practice tattoo removal or more-invasive procedures will need to cease this part of their business or move it under a medical umbrella if a doctor finds these operators to have sufficient qualifications and experience and is happy to assume such responsibility. We believe this to be in the interests of public safety.

It is also likely that some operators will find it difficult to pass the required laser safety courses and will therefore be unable to continue to provide such services. It is worthwhile noting that all such examinations for such courses should therefore be in-person examinations to ensure the identity of the participants.

The CPCA noted that there was some variance in how pigmented conditions were mentioned in this document. While “some” pigmentary disorders were mentioned as requiring medical clearance in the discussion, Appendix A mentions “pigmentary conditions” as requiring such clearance. It must be stressed that a non-medical person is assumed to not have the ability to diagnose which lesions to not treat and should be also assumed to not have the ability to know which lesions are treatable. Therefore, ALL pigmentary conditions would require medical clearance.

***Stakeholders are invited to provide feedback on whether there is sufficient case for government intervention based on the nature and magnitude of the problem.***

The CPCA believes that government intervention is long overdue and we support Option 3 of those presented here. The development of new lasers, light sources and other energy-based devices (such as radio-frequency devices) is ongoing and the RHC may need to review this regulation more frequently than every 10 years.

It is imperative that regulation includes ALL lasers and intense pulsed light sources used for cosmetic and beauty therapy treatments, not just those that are Class 4 or Class 3B, to avoid the problem of distributors selling “under the radar” to those who are not qualified to use them.

The CPCA would like to congratulate ARPANSA on its work in co-ordinating the various stakeholders to formulate the options upon which the various groups and individuals may comment. Hopefully, from this consultation process a workable solution will be brought forth which will reduce the injuries resulting from incorrect use of lasers and intense pulsed light sources. The CPCA feels only Option 3 would fulfil this need.

Yours faithfully

**COSMETIC PHYSICIANS COLLEGE  
OF AUSTRALASIA LTD**



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