16 August 2021

Dr Carl-Magnus Larsson
Chief Executive Officer
ARPANSA
619 Lower Plenty Road
Yallambie VIC 3085

Re: Investigating the public health impact of cosmetic non-ionising radiation (NIR) devices

Dear Dr Larsson,

We are writing regarding non ionising (NIR) devices applied to cosmetic and medical procedures. The Radiation Health and Safety Advisory Council ("the Council") has noted a steady flow of concern on the issue of safety of cosmetic treatments by application of non-ionising radiation (NIR) to achieve a desired aesthetic outcome, as demonstrated by consistent periodic media attention and advocacy to implement regulatory oversight by various interest groups within the beauty therapy industry. Further, there is currently a growing expansion of the cosmetic treatment market in Australia using emerging modalities such as radiofrequency and ultrasound devices or a combination of these with traditional intense optical sources. These NIR devices can be commonly categorised by the intense energy exposure resulting from their application, resulting in a potential risk of injury, particularly when misused.

The last major effort to gain understanding of the extent of potential health issues from NIR cosmetic devices was conducted in 2015-2017 as part of ARPANSA's Consultation Regulatory Impact Statement (RIS) for the use of lasers and IPLs in the beauty therapy and cosmetic industry. A survey conducted as part of the justification for considering options for a national regulatory framework for the use of these devices reported that there were 432 instances of injuries within a 12-month period as a result of improperly performed treatments. The survey had an estimated response covering 10 per cent of the industry alluding to a wider issue than that reported. However, at the conclusion of the consultation process, there was still a lack of verified data about the number and severity of the injuries from NIR cosmetic devices. This verified data would have been crucial as key evidence for any further consideration of implementing a regulatory framework, around the use of optical devices, based on the risk.

In 2020, the International Commission on Non-ionizing Radiation Protection (ICNIRP) released a Statement on NIR cosmetic devices which addressed the state of scientific and health evidence for the risk of adverse health outcomes and complications. ICNIRP's statement concluded that, although there was some evidence for adverse health outcomes and particular groups were at greater risk of complications, the scientific evidence was limited. A review of the literature included within the statement reported that most studies were limited to case-series and case reports with small sample sizes and that randomized clinical trials were lacking. Further, the majority of studies focussed on efficacy of treatment rather than adverse health outcomes and have been conducted by clinicians and consultants with direct involvement in providing treatment.

In order to address the continued advocacy for regulatory intervention and the shortfall in evidence for justifying a pathway forward to a satisfactory decision for stakeholders, the Council in its April 2021 meeting proposed that a call for further targeted research is endorsed with the aim of gathering objective, verifiable data on the health burden of injuries resulting from the use of cosmetic NIR devices. The Council recommends that this research is conducted by academic institutions or other organisations with relevant expertise in health.

The Council is aware that the Health Impact Assessment team within ARPANSA's Assessment and Advice Section has previously co-ordinated similar research in collaboration with academic institutions. Given that ARPANSA's Health Impact Assessment team also led the analysis of the 2017 RIS and the 2020 ICNIRP statement, the Council's view is that it is also well-credentialed to co-ordinate further research in this area.

Kind regards

Dr Roger Allison
Chair
Radiation Health and Safety Advisory Council