Submission No 7

COSMETIC HEALTH SERVICE COMPLAINTS IN NEW SOUTH WALES

Organisation: Australian Department of Health

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Australian Government
Department of Health

Deputy Secretary

Mr Adam Crouch, MP
Chair, Committee on the Health Care Complaints Commission
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Our Reference: D18-10174540

Dear Mr Crouch

Inquiry into cosmetic health service complaints in NSW

Thank you for the opportunity to make a submission to the Inquiry into cosmetic health service complaints in NSW (the Inquiry). The department's submission is confined to terms of reference (a) and (c).

(a) The roles and responsibilities of the Health Care Complaints Commission relative to the roles and responsibilities of Commonwealth and other state regulatory agencies;

Roles and responsibilities of the Therapeutic Goods Administration (TGA)

The Therapeutic Goods Administration (TGA) is part of the Commonwealth Department of Health, and regulates supply, import, export, manufacturing and advertising of therapeutic goods, including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products, to ensure such goods available for supply in Australia are safe and fit for their intended purpose. The TGA administers the *Therapeutic Goods Act 1989* (the Act), and associated regulations.

Regulation of therapeutic goods occurs through: pre-market assessment (therapeutic goods must be entered in the Australian Register of Therapeutic Goods (ARTG) before they can be supplied in Australia), post-market monitoring and enforcement of standards, licensing of Australian manufacturers and verifying overseas manufacturers' compliance with the same standards as their Australian counterparts.

It's beyond the TGA's power to regulate cosmetics, chemicals, or healthcare professionals (practice), and to give clinical advice regarding medicines, health

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products or treatments (www.tga.gov.au/what-tga-doesnt-do). The National Industrial Chemicals Notification and Assessment Scheme (www.nicnas.gov.au) regulates cosmetics and chemicals, while the Australian Health Practitioner Regulation Agency (www.ahpra.gov.au) supports 15 National Boards that are responsible for regulating the health professions (www.ahpra.gov.au/National-Boards.aspx). However, a number of products used in cosmetic procedures are considered to be therapeutic goods and are therefore regulated by the TGA. An example of these is dermal fillers which, for the purposes of supply in Australia, are regulated as medical devices; the majority of which are absorbable high-risk (Class III) devices.

There are a number of dermal fillers currently included on the ARTG which are generally recommended for correction of wrinkles, redefining the shape of the lips or cheeks, or tissue support. It is globally accepted convention that dermal fillers are regulated as medical devices rather than medicines because their primary intended action is not considered to be by pharmacological, chemical, immunological or metabolic means, but rather as an injectable implant.

The import, export, manufacture, supply and use of cosmetic therapeutic goods in the Australian marketplace involves compliance across multiple jurisdictions. While the TGA is responsible for import, export, manufacture and supply at the Federal level, states and territories are responsible for similar matters within their respective jurisdictions, as well as health professionals and practice.

Dermal fillers, while regulated as medical devices, may contain substances like hyaluronic acid, polyacrylamide and polylactic acid. When used in preparations for injection or implantation for tissue augmentation or for cosmetic use, they are all listed within Schedule 4 (prescription only) of the Poisons Standard. Therefore prescribing, supply and use of these substances should be conducted in accordance with relevant state or territory legislation.

The advertising of therapeutic goods to consumers and health practitioners is controlled by statutory measures administered by the TGA and self-regulation through codes of practice administered by the relevant therapeutic goods industry associations. Advertisements for therapeutic goods in Australia are subject to the requirements of the Act and Therapeutic Goods Regulations 1990, and other relevant laws including the *Competition and Consumer Act 2010*.

In general, the advertising to the public of 'prescription medicines' (Schedule 4) or 'controlled drugs' (Schedule 8) and certain 'pharmacist-only medicines' (Schedule 3 of the Poisons Standard) is prohibited by the therapeutic goods legislation. Exceptions to this are set out in the therapeutic goods legislation.

The purpose of these requirements is to protect public health by promoting the safe use of therapeutic goods and ensuring that they are honestly promoted as to their benefits, uses and effects. Controls are placed on the advertising of therapeutic goods (medicines and medical devices) to ensure advertisements are socially responsible, truthful, appropriate and not misleading.

(c) The opportunities for collaboration with other agencies, organisations and levels of Government to improve outcomes for the public in the cosmetic health services sector

The TGA believes that ongoing collaboration with other agencies, organisations and levels of Government is important for improving outcomes for the public. While various health and consumer regulators have regularly shared information, and met on a bilateral or multilateral basis in the past, a further step has been taken to form a working group of health regulators.

In April 2017, the Consumer Health Regulators Group (the Group) was established to facilitate even greater collaboration in the public interest. The Group consists of the Australian Competition and Consumer Commission (ACCC), the Australian Health Practitioner Regulation Agency (AHPRA), the Private Health Insurance Ombudsman, the TGA, and the NSW Health Care Complaints Commission (NSW HCCC). Group members meet quarterly (or otherwise as needed) and exchange information, including about emerging issues of interest or concern, and ensure the responsibilities and functions of each regulator are understood and consistently applied.

A recent example of interjurisdictional collaboration facilitated under this Group arose when concerns were raised about unsafe and illegal practices within some beauty and cosmetic clinics, including incidents of unregistered persons conducting cosmetic procedures in NSW.

In response the TGA has established a plan of actions to address regulatory non-compliance in relation to cosmetic injectables. The Cosmetic Industry Regulatory Compliance Plan 2017-18 (the Plan) targets unapproved, unregistered and counterfeit therapeutic goods used in the cosmetic industry, and sets out a series of activities to mitigate the compliance risks in the regulation of dermal fillers, and the labelling of these medical devices. There are three major streams of activity: actions relating to the regulation of this type of medical device; compliance initiatives; and advertising matters. Examples include:

- Regulation of medical devices
  - Legislative changes are being prepared to clarify that information provided with the medical device (including labels) must comply with the Poisons Standard. A guidance document is nearing finalisation that explains which devices are required to comply with the Poisons Standard and how the requirements should be met.

- Importation
  - We have updated the Therapeutic Goods Priority Target Profile provided to Australian Border Force (ABF) to include relevant products. We are liaising with ABF on aspects of the Plan.

- Advertising
  - We have issued 166 letters and factsheets to advertisers of botox products that have been the subject of advertising complaints.

These activities are being complemented by education initiatives such as a web statement, consumer factsheet and social media posts.

The Plan has been provided to NSW Health and NSW HCCC for input. NSW Health and the TGA have begun sharing information for the production of an intelligence product to facilitate future investigations and compliance activities. We plan to build on this experience to facilitate future collaborative intelligence, compliance, and investigative activities as matters are identified for cooperative action in the future.

NSW HCCC have proposed the development of a protocol with the Group that supports the bringing together of different regulatory agencies on areas of joint interest and priority. The TGA supports a protocol that provides information on each agency and their powers, ensuring the right agencies are brought into matters, and facilitates joint operations through agreed principles, including on information exchange, without inhibiting our ability to collaborate as required. In our view, this would provide an improved capability to disrupt the type of activity which isn't readily able to be addressed through individual state based responses or health regulation alone, therefore providing even greater protections to the Australian community.

I would like to take this opportunity to congratulate the NSW HCCC for their work to combat growing issues within the cosmetic health industry, and the TGA looks forward to working with them into the future.

Thank you again for your invitation to provide a submission to the Inquiry. Please don't hesitate to contact me if you require any further information.

Yours sincerely

[redacted]

Adj. Professor John Skerritt
Health Products Regulation Group

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