Australian Government
Department of Health
Therapeutic Goods Administration

Consumer Health Regulators Group

Pre Meeting Update February 2018

The following update is offered on a number of the matters highlighted in the email to members on 12 January 2018 requesting information on key issues ahead of the planned meeting on 15 February 2018.

Cosmetic Industry

The TGA has established a plan of actions covering regulation, compliance, advertising and education, to address regulatory non-compliance and patient safety in relation to cosmetic injectables.

Dermal fillers are regulated as medical devices in Australia, the majority of which are absorbable high-risk Class III devices. In order to ensure that medical device manufacturers and sponsors meet the labelling requirements of the Poisons Standard, an amendment to the regulatory framework is proposed, through amendment to the Therapeutic Goods (Medical Devices) Regulations 2002, to specify that the information supplied with the device must comply with the Poisons Standard. A condition to current ARTG entries (~65 through 10 sponsors) would be added to require compliance with the Poisons Standard during the transition period.

The regulatory compliance area has provided the Australian Border Force (ABF) with a target list of products for identification at international mail gateways including air and sea cargo. Currently [redacted] Where importations are not compliant with the Therapeutic Goods Act and associated Regulations, they will be forfeited, seized and destroyed. Significant imports or recidivist entities may be prosecuted where sufficient evidence is available. In collaboration with ABF we are also planning to target international aircraft passenger arrivals across key Australian airports.

On 22 December the Deputy Secretary of TGA sent letters to all State and Territory health departments, re-enforcing the jurisdictional responsibilities of stakeholders, outlining how cosmetic injectables are regulated as medical devices, and invited State and Territory health departments to respond with any specific issues they have experienced in relation to dermal filler products in their respective jurisdictions. These letters followed a joint operation in NSW mid-December 2017 with the NSW Health Care Complaints Commission and NSW Health.

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The Advertising Compliance Unit is sending regulatory obligation letters and educational material to advertisers who have come to our attention for advertising Botox and other injectable beauty products. We will also work with peak bodies to further disseminate educational materials.

Other education actions include the development of guidance on compliance with the Poisons Standard and correspondence with the ~10 sponsors of these devices, along with a proposed agenda item at the upcoming Regulatory and Technical Forum with key industry stakeholders.

In order to reach consumers regarding the risks associated with using cosmetic injectable therapeutic goods we are planning a web statement and social media posts around the following key messages:

- The process of injecting dermal fillers is a medical procedure that should only be undertaken by an experienced and qualified medical doctor, or a nurse under a doctor's supervision
- Only products approved by the TGA should be used
- Neither the brands of products nor the substances used for dermal filling can be advertised to the public. Brands should be discussed in consultations to ensure the doctor uses good quality products
- Risks are not only associated with the product. Doctors who lack adequate experience, qualifications and knowledge can cause significant adverse events.

Peptides

TGA in collaboration with ABF and the Australian Sports Anti-Doping Authority have been targeting the importation and supply of peptides since November 2017. A joint operation was undertaken in Queensland in December 2017 where [redacted]

Advertising

The Advertising Compliance Unit is working on the implementation of reforms to the advertising framework arising from the Review of Medicines and Medical Devices Regulation, for commencement on 1 July 2018. Legislative amendments to the *Therapeutic Goods Act 1989* are currently before Parliament. The advertising-related amendments can be found in Schedule 6 of the Bill and:

- Improve consistency across the regulation of advertising of different types of therapeutic goods and repeal the requirement for complementary and over-the counter medicine advertisements to be approved prior to publication or broadcast;
- Provide provisions to support the TGA as the single body responsible for implementing a more transparent and efficient complaints management process; and
- Provide for an improved sanctions and penalties regime to deter inappropriate advertising, and that supports the TGA to take effective actions over contraventions of advertising requirements.

The amendments to the Act will be accompanied by an education program to assist industry sponsors and advertisers in understanding their obligations.