

Application of Better Regulation Principles

Poisons and Therapeutic Goods Amendment (Cosmetic Use) Regulation 2021

Principle 1 - The need for government action should be established

The amendments would regulate the use of cosmetic medicines to help better protect the public. The *Poisons and Therapeutic Goods Act 1966* was amended in 2018, following the Ministry of Health's *Report on the Review of the Regulation of Cosmetic Procedures* (the Ministry Report). The amendments allowed regulations to be made to set tailored rules in respect of the medicines commonly used in cosmetic procedures.

The Ministry Report was conducted following the 2017 death of Ms Jean Huang following the administration of local anaesthetic and breast fillers as part of a beauty procedure. The *Poisons and Therapeutic Goods Amendment (Cosmetic Use) Regulation 2021* creates tailored rules by setting requirements for the administration, storage, and record keeping of medicines commonly used for cosmetic purposes (botulinum toxins; hyaluronic acid and its polymers; deoxycholic acid; polyacrylamide; and polylactic acid, calcium hydroxylapatite, collagen; and polycaprolactone).

The key amendment would prohibit persons from administering these substances unless they are a nurse acting under the direction of a medical practitioner or nurse practitioner. The restriction doesn't apply where the administration is undertaken by an *authorised practitioner* themselves (acting within scope of their professional practice), or by an employee in a hospital acting on an *authorised practitioner's* direction.

Principle 2 - The objective of government action should be clear

The Amending Regulation seeks to increase the regulation of the use of cosmetic medicines and help better protect the public. Many of the substances used in cosmetic procedures are prescription-only medicines that are prone to misuse or supplied outside normal medical models of care. The Amending Regulation clearly requires administration of these substances to occur by a nurse on the direction of an authorised practitioner. Further, businesses that provide these services are under an obligation to ensure that there are appropriate risk management policies and procedures in place to protect the health and safety of patients, and appropriate equipment available for use in a patient medical emergency. The Amending Regulation seeks to implement amendments to address concerns raised in the Ministry Report as to whether authorised practitioners who prescribe these medicines have appropriate oversight over the receipt, storage, access, use and administration of these medicines.

Principle 3 - The impact of government action should be properly understood by considering the costs and benefits of a range of options, including non-regulatory options

The amendments prescribe requirements for the administration and storage of certain substances used for cosmetic purposes. There is no non-regulatory way to implement the changes.

Principle 4 - Government action should be effective and proportional

The amendments implement targeted regulation of substances commonly used in cosmetic procedures. The Amending Regulation is considered to be effective and proportional to address the risk of administration of these substances by persons who are not an authorised practitioner or a nurse.

Principle 5 - Consultation with businesses and the community should inform regulatory development

The Ministry of Health has engaged in a thorough consultation process with stakeholders and the general public. The Ministry conducted initial consultation on proposed changes in late 2018. A Consultation Draft of the Amending Regulation was prepared for the purpose of further public consultation, including targeted written consultation with stakeholders and publication on the NSW

Government *Have Your Say* website, which was conducted between January and April 2020. The Ministry has since undertaken further consultation with the Medical Services Committee and the Australian Medical Association, which both support the amendments.

Principle 6 - The simplification, repeal, reform, consolidation of existing regulation should be considered

The Amending Regulation amends the existing PTG Regulation.

Principle 7 - Regulation should be periodically reviewed, and if necessary reformed to ensure its continued efficiency and effectiveness

The PTG Regulation is subject to the standard five-yearly staged repeal under the Subordinate Legislation Act 1989.