The Optometry Board of Australia's Patient and Consumer Health and Safety Impact Assessment for the revised *Guidelines for use of scheduled medicines*

September 2021

Assessment purpose

The National Boards' Patient and Consumer Health and Safety Impact Assessment[1] explains the potential impact of a proposed registration standard, code or guideline on the health and safety of the public, vulnerable members of the community and Aboriginal and Torres Strait Islander Peoples.

The four key components considered in the Assessment are:

1. The potential impact of the revised registration standard, code or guideline on the health and safety of patients and consumers particularly vulnerable members of the community including approaches to mitigate any potential negative or unintended effects
2. The potential impact of the revised guideline on the health and safety of Aboriginal and Torres Strait Islander Peoples including approaches to mitigate any potential negative or unintended effects
3. Engagement with patients and consumers particularly vulnerable members of the community about the proposal
4. Engagement with Aboriginal and Torres Strait Islander Peoples about the proposal.

The National Boards' Health and Safety Impact Assessment aligns with the *National Scheme's* *Aboriginal and Torres Strait Islander Cultural Health and Safety Strategy 2020-2025*, *National Scheme engagement strategy 2020-2025*, National-Scheme-Strategy 2020-2025 and reflect key aspects of the revised consultation process in the AManC Procedures for developing registration standards, codes and guidelines and accreditation standards.

[1] This assessment has been developed by Ahpra and the National Boards in accordance with section 25(c) and 35(c) of the *Health Practitioner Regulation National Law* as in force in each state and territory (the National Law). Section 25(c) requires AHPRA to establish procedures for ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice. Section 35(c) assigns the National Boards functions to develop or approve standards, codes and guidelines for the health profession including the development of registration standards for approval by the COAG Health Council and that provide guidance to health practitioners registered in the profession. Section 40 of the National Law requires National Boards to ensure that there is wide-ranging consultation during the development of a registration standard, code, or guideline.

Below is our assessment of the impact of [the proposal] on the health and safety of [patients and consumers], particularly vulnerable members of the community, and Aboriginal and Torres Strait Islander Peoples.

1. How will the proposal impact on patient and consumer health and safety, particularly vulnerable members of the community? What are the actions that have been taken to address or prevent this?

The Optometry Board of Australia's (the Board) proposal to is expected to have a small but positive impact on patient health and safety.

In response to targeted consultation feedback, the Board will amend Appendix B of the existing Guidelines to include:

-the topical scheduled 4 medicine, Lifitegrast, and

-a footnote that states "Endorsed optometrists must be familiar with the Black Triangle Scheme and report any adverse events involving listed medicines which are included in the Black Triangle Scheme. Further information may be found at https://www.tga.gov.au/black-triangle-scheme and guideline section 2.5."

The Board identified a range of potential benefits and costs of the proposal, and undertook a targeted consultation using tailored approaches with peak professional bodies, safety and community groups and government health departments. The purpose of the targeted consultation was to seek feedback on a proposed change, adding a topical schedule 4 medicine, Lifitegrast, to the Board approved scheduled medicines list for endorsed optometrists in Appendix B of the Optometry Board of Australia's (the Board) *Guidelines for the Use of Scheduled Medicines* (the Guidelines).

Our engagement through the targeted consultation with organisations representing vulnerable members of the community has assisted us to meet our responsibilities to protect patient safety and health care quality. Stakeholders who were sent the proposal included a range of stakeholders in the safety, patient and consumer fields. Feedback from these groups supported the Board's view that the change would result in improved access to primary dry eye care, particularly in rural and remote areas where access to specialist eye care may be limited.

We have carefully considered feedback to identify any unintended impacts, including potential negative impacts for the proposal. We will continue to engage with patient safety and consumer groups in order to get input and views from vulnerable members of the community.

2. How will this proposal impact on Aboriginal and Torres Strait Islander Peoples? What are the actions that have been taken to address or prevent this?

The Board has carefully considered any potential impact of the proposal on Aboriginal and Torres Strait Islander Peoples and how the impact compared to non-Aboriginal and Torres Strait Islander Peoples might be different. We believe the proposal to add Lifitegrast to the list of approved medicines for optometrists will have a small but positive impact on Aboriginal and Torres Strait Islander Peoples health and safety given the potential for improved access through primary care providers.

A limiting factor identified through consultation was the relative cost of Lifitegrast, which is not subsidised under in the Pharmaceutical Benefits Scheme. Patients must therefore pay the full cost of the medicine; however this issue is outside of the Board's jurisdiction under the National Law.

Consultation also identified the capacity to reduce potential negative impacts for patients where adverse events are recorded. In response to feedback, the Board has amended wording to strengthen the requirement that optometrists must be familiar with the Therapeutic Goods Administration's (TGA) Black Triangle Scheme and report any adverse events to allow for quick identification of new medicine safety information.

The Board is committed to the National Scheme's Aboriginal and Torres Strait Islander Health and Cultural Safety Strategy 2020-2025 which focuses on normalising patient safety for Aboriginal and Torres

Islander Peoples, and the inextricably linked elements of clinical and cultural safety. As part of the consultation process, we have tried to find the best way to engage with Aboriginal and Torres Strait Islander Peoples in a meaningful way. We will continue to engage with Aboriginal and Torres Strait Islander organisations and stakeholders in order to continue to get their input and views on future iterations of the Guidelines for use of scheduled medicines, and other policy reviews.

Continuing to engage with relevant organisations and Aboriginal and Torres Strait Islander Peoples will help us to identify any other future impacts of the Guidelines, and these will be considered on an ongoing basis and in future reviews.

3. How will the impact of the proposal be actively monitored and evaluated?

Part of the Board's work in keeping the public safe is ensuring that all Board guidelines are regularly reviewed. Under the Board's Code of Conduct, the Board also highlight that optometrists have a responsibility to recognise and work within the limits of their competence and know when to refer to another practitioner. The Board's Registration and Notification Committee actively monitors notifications of registered optometrists, including notifications relating to prescribing.

Outside of the Board's jurisdiction, the TGA will continue to monitor adverse events related to medicines, including Lifitegrast to safeguard and enhance the health of the Australian community. The Black Triangle Scheme encourages practitioners and consumers to report any adverse reactions to allow for quick identification of medicine safety information, for new medicines.