EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard Amendment (Hydroxychloroquine) Instrument 2020

The *Therapeutic Goods Act 1989* ("the Act") provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act also provides a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and to ensure the safe handling, of medicines and poisons in Australia. The Act is administered by the Therapeutic Goods Administration ("the TGA"), within the Australian Government Department of Health.

Part 6-3 of the Act provides the basis for a uniform system of access controls for goods containing scheduled substances. The scheduling of substances allows restrictions to be placed on the supply of those substances to the public, in the interests of public health and safety, to minimise the risks of poisoning from, and the misuse or abuse of, scheduled substances.

Subsection 52D(2) of the Act provides that the Secretary may amend the current Poisons Standard or prepare a document ("a new Poisons Standard") in substitution for the current Poisons Standard. The current Poisons Standard classifies substances in a number of schedules, with each schedule signifying the degree of risk and the recommended controls for the availability of those substances to the public.

Section 52E of the Act specifies the matters the Secretary must take into account when exercising the power under subsection 52D(2) of the Act. In accordance with subsection 52E(1), these matters include (among other matters), the risks and benefits of the use of a substance, the purposes for which a substance is to be used and the extent of use of a substance, the toxicity of a substance, and the potential for abuse. In accordance with subsection 52E(3), the Secretary must also have regard to any recommendations of the Advisory Committee on Medicines Scheduling ("the ACMS") and the Advisory Committee on Chemicals Scheduling ("the ACCS"), established under sections 52B and 52C of the Act respectively.

The Scheduling Policy Framework ("the SPF") provides guidance on whether a decision concerning the scheduling of substances would benefit from the advice of the ACMS or ACCS. The SPF is available on the TGA website.

State and Territories regulate the supply of medicines and poisons by incorporating the schedules contained in the current Poisons Standard in State and Territory laws. This ensures there is a uniform system of restrictions in Australia relating to the supply of scheduled substances, based on the risks associated with use of those substances and the recommended level of controls over availability.

The purpose of the *Poisons Standard Amendment (Hydroxychloroquine) Instrument 2020* ("the Amendment Instrument") is to amend the *Poisons Standard February 2020* in relation to the substance hydroxychloroquine. These amendments principally allow dental practitioners who are registered specialists in oral medicine to authorise the supply of hydroxychloroquine in the treatment of patients. This is in addition to the categories of specialist medical practitioners currently permitted to authorise the supply of hydroxychloroquine under the *Poisons Standard February 2020*.

Hydroxychloroquine is a substance that has been used for the prevention and treatment of certain types of malaria, rheumatoid arthritis and other conditions. Recent studies have suggested that

hydroxychloroquine may have potential in the treatment of the disease known as coronavirus disease (COVID-19). Recent reports of increased prescribing of medicines containing hydroxychloroquine in light of the coronavirus disease (COVID-19) emergency have raised concerns regarding a potential shortage of these medicines in Australia.

The *Poisons Standard Amendment (Hydroxychloroquine and Salbutamol) Instrument 2020* ("the Former Amendment Instrument") commenced on 24 March 2020 and amended the *Poisons Standard February 2020* in relation to hydroxychloroquine and another substance, salbutamol, to address concerns relating to the availability of medicines containing such substances in light of the coronavirus disease (COVID-19) emergency.

The Former Amendment Instrument addressed such concerns in relation to hydroxychloroquine by including this substance in Appendix D to the Poisons Standard. Appendix D specifies additional controls on possession or supply of certain substances when included in Schedule 4 or 8 to the Poisons Standard. In particular, the amendments specified that, in addition to the requirement to supply medicines containing hydroxychloroquine on prescription, a medical practitioner recognised under the Health Practitioner Regulation National Law as a specialist in dermatology, emergency medicine, intensive care medicine, paediatrics and child health, or a physician must authorise the supply of the substance in the initial treatment of a patient following the commencement of the Former Amendment Instrument (on 24 March 2020).

Following authorisation of the initial treatment by a medical practitioner recognised in one of these specialties, the ongoing supply of hydroxychloroquine for the treatment of the patient may be authorised by prescription of a general practitioner.

The Amendment Instrument amends the *Poisons Standard February 2020* to specify an additional category of specialist health practitioner for the purpose of the authorisation of supply of hydroxychloroquine in the initial treatment of patients, namely, a dental practitioner registered under State or Territory legislation as a specialist in oral medicine. It is appropriate that these specialists be able to continue to prescribe hydroxychloroquine in the treatment of patients with conditions such as ulcerative oral lichen planus.

By restricting the supply of hydroxychloroquine for the initial treatment of a patient to authorisation by a dental practitioner registered as an oral medicine specialist under State and Territory legislation, the Amendment Instrument seeks to support the continued availability of medicines containing this substance during the public health emergency caused by the COVID-19 emergency and to prevent its inappropriate use in Australia.

The Amendment Instrument also makes minor editorial amendments to item 8 of Appendix of the *Poisons Standard February* 2020, principally to clarify that the medical practitioners mentioned in that item must be registered in certain recognised specialties under State or Territory legislation that forms part of the Health Practitioner Regulation National Law ("the National Law"). The Amendment Instrument thereby ensures consistency with the references to specialist registration in section 270 of the National Law.

The Amendment Instrument reflects a decision to amend the current Poisons Standard by a delegate of Secretary on their own initiative and was not open to public consultation. However, the ACMS (including State and Territory representative members) was consulted and supported the amendment. Further, it was considered necessary to make the Amendment Instrument urgently in order to support the continued availability of medicines containing hydroxychloroquine for Australian patients and to support the Australian Government's response to the COVID-19 public health emergency.

The Amendment Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*. However, section 42 of the *Legislation Act 2003* relating to disallowance does not apply (subsection 52D(4A) of the Act refers). As the Amendment Instrument is not disallowable, subsection 9(1) of the *Human Rights (Parliamentary Scrutiny) Act 2011* does not require the instrument to be accompanied by a statement of compatibility with the human rights recognised under that Act.

The Amendment Instrument commences on the day after it is registered.