

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Poisons Standard Amendment (Hydroxychloroquine and Salbutamol) 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 State and Territory governments 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 (sections 52AA to 52EC) provides the basis for a uniform system of controls for goods containing scheduled substances. The scheduling of substances allows restrictions to be placed on their supply to the public, in the interests of public health and safety. The scheduling of substances is aimed at minimising the risks of poisoning from, and the misuse or abuse of, scheduled substances.

Subsection 52D(2) of the Act empowers the Secretary to amend the current Poisons Standard or to prepare a document (“a new Poisons Standard”) that includes schedules containing the names or descriptions of substances, in substitution for the current Poisons Standard. The current Poisons Standard consists principally of the Standard for the Uniform Scheduling of Medicines and Poisons (section 2 of the Poisons Standard refers). It reflects decisions of the Secretary or a delegate of the Secretary regarding the classification of medicines and poisons into the different Schedules, signifying the degree of risk and the control recommended to be exercised over their availability to the public.

The Act establishes two expert advisory committees, the Advisory Committee on Medicines Scheduling (“ACMS”) (section 52B of the Act refers) and the Advisory Committee on Chemicals Scheduling (“ACCS”) (section 52C of the Act refers). ACMS and ACCS provide advice and make recommendations to the Secretary on matters relating to medicines and chemicals scheduling decisions.

The Schedules contained in the Poisons Standard are referred to under State and Territory legislation for regulatory purposes. This enables restrictions to be placed on the supply of scheduled substances to the public, according to the degree of risk associated with the substances and the level of control recommended over their availability, in the interest of public health and safety.

The Commonwealth takes into account the scheduling and classification of substances in the Poisons Standard for regulatory and enforcement purposes under the Act. For example, the Act prohibits the publication or broadcasting of advertisements to consumers about prescription medicines containing substances included in Schedule 4 or Schedule 8 to the Poisons Standard, or over-the-counter medicines containing substances included in Schedule 3 and not included in Appendix H of the Poisons Standard. The advertising of substances included in Schedule 9 or Schedule 10 to the Poisons Standard is also prohibited.

The Scheduling Policy Framework (“the SPF”) provides guidance on whether a decision concerning the scheduling of substances under the Poisons Standard would benefit from being referred to ACMS or ACCS for advice. A copy of the SPF can be found at <https://www.tga.gov.au/publication/ahmac-scheduling-policy-framework-medicines-and-chemicals>.

The purpose of the *Poisons Standard Amendment (Hydroxychloroquine and Salbutamol) Instrument 2020* (“the Amendment Instrument”) is to amend the *Poisons Standard February 2020* in relation to the substances, hydroxychloroquine and salbutamol, principally to ensure the continued availability of medicines containing these substances in Australia during the public health emergency caused by the outbreak of the disease known as coronavirus disease (COVID-19).

Hydroxychloroquine is a substance that has been used in medicines for the prevention and treatment of certain types of malaria, rheumatoid arthritis and other conditions. Recent studies have indicated that hydroxychloroquine may have potential in the treatment of COVID-19. Recent reports of increased prescribing of medicines containing hydroxychloroquine have raised concerns regarding a potential shortage of these medicines in Australia. Consequently, there is a need to ensure availability of supply for those patients who need to use medicines containing hydroxychloroquine and to prevent inappropriate use. Hydroxychloroquine is included in Schedule 4 to the Poisons Standard, indicating that the recommended level of control for this substance is that it be available to persons with a prescription.

Salbutamol, also known as albuterol or Ventolin, is a bronchodilator and adrenoreceptor stimulant used in medicines that are indicated for the treatment of asthma. Concerns have arisen that such medicines have been the subject of panic-buying and hoarding in association with COVID-19, and that there is a corresponding need to ensure availability of supply for those patients who genuinely need to use such medicines for their asthma condition. Salbutamol is included in Schedule 3 to the Poisons Standard, indicating that the recommended level of control for this substance is that it requires professional advice but should be available to the public from a pharmacist, without a prescription.

The Amendment Instrument would address the concerns relating to both of these substances, by:

- in relation to hydroxychloroquine—including a reference to the substance in Appendix D to the Poisons Standard, to specify that, in addition to the requirement to supply a medicine containing the substance on prescription, a Medical Board of Australia recognised specialist in dermatology, intensive care medicine, paediatrics and child health, a physician or a specialist in emergency medicine has authorised the supply of the substance in the initial treatment of a patient following the commencement of the Amendment Instrument. The intention is to ensure that patients first obtain an authorisation for initial treatment from a medical practitioner recognised by a Medical Board of Australia as a specialist in one of the specialities mentioned in item 8 of Appendix D before being able to obtain ongoing authorisation from their general practitioner; and

- in relation to salbutamol—substituting a new entry for this substance in Schedule 3 to the Poisons Standard, to specify that its supply is limited to persons with evidence of a medically diagnosed lung condition, persons with a record of previous supply from the same pharmacist, persons authorised under a law of a State or Territory to supply or supply salbutamol in the practice of their profession (such as medical practitioners) or for use in institutional first aid (for example, schools and workplaces). The new entry would also specify that supply is limited to one primary pack of salbutamol for each person with evidence of a medically diagnosed lung condition or previous supply from the pharmacist.

The Amendment Instrument also makes two minor, consequential amendments to the *Poisons Standard February 2020* to support the first measure mentioned above by including a hash symbol (#) in the Schedule 4 entry for hydroxychloroquine to indicate that there is also an Appendix D entry for this substance, and to update the reference to hydroxychloroquine in the index to reflect the new Appendix D entry.

These decisions were delegate-only decisions that were not open to public consultation. However, the ACMS (including State and Territory representative members) was consulted and supported these amendments. Further, it was considered necessary to put these decisions in place urgently in order to support the continued availability of these medicines for Australians who need to use them and to support 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 *Legislation Act 2003* 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.