Australian Government
Department of Health
Therapeutic Goods Administration

Notice of an amendment to the current Poisons Standard under paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989*

24 March 2020

This web publication constitutes a notice on amendments to the current Poisons Standard made by a delegate of the Secretary pursuant to paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989* (the Act). This notice publishes:

- amendments to the current Poisons Standard made by a delegate of the Secretary;
- the reasons for those amendments; and
- the date of effect of those amendments.

1.1. Amendment in relation to hydroxychloroquine

Amendment

For the reasons set out below, a delegate of the Secretary of the Department of Health under paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989* (the Act), has decided to exercise their power under that paragraph to amend the current Poisons Standard (the *Poisons Standard February 2020*) to include an Appendix D listing for hydroxychloroquine as follows:

Appendix D, Item 8

8.	**Poisons for which the initial treatment of a patient has been authorised following the commencement of the *Poisons Standard Amendment (Hydroxychloroquine and Salbutamol) Instrument 2020* by a medical practitioner, recognised under State or Territory legislation that forms part of the Health Practitioner Regulation National Law, as a specialist in any of the following:** **(a) dermatology;** **(b) intensive care medicine;** **(c) paediatrics and child health;** **(d) physician;** **(e) emergency medicine.**
	HYDROXYCHLOROQUINE.

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HYDROXYCHLOROQUINE

Schedule 4
Appendix D, Item 8

This amendment should be read in conjunction with the current Poisons Standard (https://www.legislation.gov.au/Details/F2020C00148).

Date of effect of the amendment

24 March 2020

Material considered

In relation to this amendment to the current Poisons Standard, the delegate considered the following:

- paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989;*
- subsection 52E(1) of the *Therapeutic Goods Act 1989*, in particular in particular (f) any other matters that the Secretary considers necessary to protect public health;
- the advice received from the Advisory Committee on Medicines Scheduling (ACMS #30) 20 March 2020;
- the Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- the Scheduling Handbook (V 1.1, July 2019).

Reasons for the amendment (including findings on material questions of fact)

I decided to amend the Poisons Standard by creating a new Appendix D listing for hydroxychloroquine. In making this amendment I considered the matters in subsection section 52E(1) of the *Therapeutic Goods Act 1989*, including in particular paragraph 52E(1)(f) in relation to other matters that the Secretary considers necessary to protect public health.

In making this amendment, I considered that in Australia and internationally individuals are seeking this medication from their health practitioners as a COVID-19 treatment/prophylaxis, creating demand shortages. This poses a serious health risk to individuals currently using this medication. I am of the view that an urgent control through the Poisons Standard was needed to regulate inappropriate use and minimise further risks caused by a medicines shortage whilst still allowing on-going use by patients already prescribed it.

I considered an Appendix D listing to be appropriate in this situation, to ensure that prescription of this medicine is limited to that initially authorised by particular specialist medical practitioners in the AHPRA recognised medical specialities of dermatology, intensive care medicine, paediatrics and child health, physician and emergency medicine. I am of the view that it is appropriate to place the restriction on initiation of therapy to minimise inappropriate use and to minimise shortages, whilst acknowledging that patients have been prescribed repeats of this for many years by non-specialist medical practitioners. These repeat prescriptions can be done by medical practitioners outside these specialities where patients have been previously prescribed it.

1.2. Amendment in relation to salbutamol

Amendment

For the reasons set out below, a delegate of the Secretary of the Department of Health under paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989* (the Act), has decided to exercise their power under that paragraph to amend the Schedule 3 entry for salbutamol in the current Poison Standard.

The amendment is to repeal the entry for salbutamol in Schedule 3 of the current Poisons Standard and substitute with the following:

Schedule 3

SALBUTAMOL as the only therapeutically active substance:

a) in metered aerosols delivering 100 micrograms or less of salbutamol per metered dose; or

b) in dry powders for inhalation delivering 200 micrograms or less of salbutamol per dose; and

where supply is limited:

c) to persons with evidence of a medically diagnosed lung condition; or

d) to persons with a record of previous supply from the pharmacist; or

e) to persons authorised under a law of a State or Territory to use or supply salbutamol in the practice of their profession; or

f) for use in institutional first aid; and

where paragraph (c) or (d) applies—supply is limited to one primary pack of salbutamol per person.

This amendment should be read in conjunction with the current Poisons Standard (https://www.legislation.gov.au/Details/F2020C00148).

Date of effect of the amendment

24 March 2020

Materials considered

In relation to this amendment to the current Poisons Standard, the delegate considered the following:

- paragraph 52D(2)(a) of the *Therapeutic Goods Act 1989;*
- subsection 52E(1) of the *Therapeutic Goods Act 1989*, in particular (f) any other matters that the Secretary considers necessary to protect public health.
- the advice received from the Advisory Committee on Medicines Scheduling (ACMS #30) 20 March 2020;
- the Australian Health Ministers' Advisory Council's Scheduling Policy Framework (SPF 2018); and
- the Scheduling Handbook (V 1.1, July 2019).

Reasons for the amendment (including findings on material questions of fact)

I decided to amend the Schedule 3 entry for salbutamol to require pharmacists to confirm that patients requesting salbutamol over-the-counter have evidence of a medically diagnosed lung condition or a record of previous supply from the pharmacist, and to limit the sale to a maximum of one pack per purchase. Salbutamol will continue to be allowed to be supplied by pharmacists for use in institutional

first aid or to persons who are authorised under state or territory law to possess it or supply it under lawful practice of their profession without the limit of one pack per person.

In making this amendment, I relied among other things on reports from pharmaceutical companies to the Therapeutic Goods Administration that, in response to the COVID-19 pandemic, the community demand for salbutamol has increased markedly. Of particular concern, I noted that suppliers reported that if the current levels of demand through excessive purchasing (stockpiling) continue, supply interruptions will occur at both the local and national level.

It is my view that, if the current levels of community demand for salbutamol continue, in particular for the intent of stockpiling, this will result in significant adverse health impacts due to the unavailability of this medicine or an interruption to treatment for patients with chronic conditions such as asthma and Chronic Obstructive Pulmonary Disease (COPD) . I find urgent control through the Poisons Standard is necessary to regulate inappropriate supply of salbutamol and to ensure access for patients with medically diagnosed clinical need.

I considered the matters under part (f) of section 52E of the *Therapeutic Goods Act 1989* to be relevant to this decision. The additional controls on salbutamol are necessary to protect public health and will ensure access for patients who require salbutamol to treat symptoms of asthma and COPD.