



Therapeutic Goods (Medicines— Hydroxychloroquine and Chloroquine) (COVID-19 Emergency) Exemption 2020

I, Caroline Edwards, as delegate of the Minister for Health, make the following exemption.

Dated 2 April 2020

Caroline Edwards
Acting Secretary
Department of Health

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1 Name

This instrument is the *Therapeutic Goods (Medicines—Hydroxychloroquine and Chloroquine) (COVID-19 Emergency) Exemption 2020*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	The day this instrument is made.	2 April 2020

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under section 18A of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in section 3 of the Act, including the following:

- (a) manufacture;
- (b) medicine;
- (c) supply.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

COVID-19 emergency means the public health emergency caused by the outbreak of the disease known as coronavirus disease (COVID-19).

Note: The World Health Organization declared the outbreak of COVID-19, formerly novel coronavirus (2019 nCoV), a Public Health Emergency of International Concern on 30 January 2020, and subsequently characterised the outbreak as a pandemic on 11 March 2020. On 18 March 2020, the Australian Government declared a human biosecurity emergency in Australia under the *Biosecurity Act 2015*.

Regulations means the *Therapeutic Goods Regulations 1990*.

specified therapeutic goods means a medicine to which each of the following paragraphs apply:

- (a) the medicine contains the active ingredient, hydroxychloroquine sulfate or chloroquine phosphate; and
- (b) the medicine does not contain any other active ingredient; and
- (c) the medicine is manufactured in appropriate dosage forms for oral administration.

5 Exemption

- (1) The specified therapeutic goods are exempt from the operation of Division 2 of Part 3-2 of the Act in order to deal with the actual threat to public health caused by the COVID-19 emergency.

Note: Under paragraph 18A(2)(b) of the Act, the Minister may make an exemption under subsection 18A(1) only if satisfied that, in the national interest, the exemption should be made so that the goods can be made available urgently in Australia to deal with an actual threat to public health caused by an emergency that has occurred.

Period of exemption

- (2) This exemption takes effect on the commencement of this instrument and ceases to have effect on 31 January 2021.

6 Conditions

This exemption is subject to the following conditions:

- (a) the specified therapeutic goods must only be imported, exported, manufactured or supplied by:
 - (i) a person under a contract between the person and the Australian Government Department of Health for that purpose; or
 - (ii) a person who has made prior written arrangement with the Australian Government Department of Health for that purpose; and
- (b) the specified therapeutic goods must only be supplied in Australia for the prevention, treatment or alleviation of coronavirus disease (COVID-19) following advice from the Australian Government Department of Health; and
- (c) the supply of the specified therapeutic goods for a therapeutic use mentioned in paragraph (b) must be accompanied by a patient information leaflet (in hard copy or electronic form) that includes the information specified in Schedule 1 relating to the therapeutic use; and
- (d) the patient information leaflet mentioned in paragraph (c) must be supplied in a manner that ensures the information is given to the person to whom the goods are administered or otherwise dispensed; and
- (e) the person mentioned in paragraph (a) must keep records in relation to the importation, exportation, manufacture and supply of the relevant specified therapeutic goods; and
- (f) on request from the Secretary, the person mentioned in paragraph (a) must make the records mentioned in paragraph (e) available to the Secretary; and

(g) the specified therapeutic goods must be stored and transported in a manner that ensures:

- (i) the security of the goods is appropriate to the level of risk that the goods pose to the public and environment; and
- (ii) the integrity of the condition of the goods is maintained.

- Note 1: There are offences and civil penalty provisions in relation to goods exempt under section 18A, including:
- (a) sections 20, 22 and 22AA (offences and civil penalties for breaching a condition of exemption);
 - (b) sections 30F and 30FA (offence and civil penalty for goods not conforming to standards);
 - (c) section 30H (offence for not keeping records);
 - (d) sections 35 and 35A (offence and civil penalty for manufacturing goods without a licence).
- Note 2: There are other provisions in the Act that apply to goods exempt under section 18A, including:
- (a) section 31AA (requirement to provide information to the Secretary);
 - (b) sections 39 and 41 (provisions relating to manufacturing goods);
 - (c) section 46A (provision enabling search of premises).
- Note 3: Regulation 12AAB and Schedule 5B of the Regulations set out arrangements for the disposal of unused emergency goods for the purposes of section 30G of the Act.

Schedule 1—Patient information leaflet

Note: See section 6.

Information to be included in a patient information leaflet

Item	Specified information
1	<ul style="list-style-type: none">(a) the name of the medicine;(b) the quantity, proportion or strength of each active ingredient;(c) the method of administration;(d) the suggested dosage and duration of treatment;(e) the suggested frequency of administration;(f) a statement that optimal dosage, duration of treatment and frequency of administration is unknown;(g) a statement regarding contraindications;(h) a statement regarding warnings, precautions and other safety measures including symptoms and recommended treatment of overdose or accidental poisoning;(i) a statement regarding the medicine's interactions with other medicines and other serious forms of interactions;(j) a statement regarding adverse or undesirable effects;(k) a statement regarding appropriate storage conditions and a reference to the expiry date;(l) the name, street address and contact details of the Australian sponsor.
