

Australian Government

Department of Health

Therapeutic Goods Administration

Coronavirus (COVID-19): Information on medicines and medical devices

2 April 2020

The TGA is publishing the latest information about medicines and medical devices as it relates to COVID-19 on this page.

If you're a supplier, health professional or consumer, please read the information below before contacting the TGA.

We are currently experiencing a high volume of calls and emails and we ask for your patience as we try to respond to queries as quickly as possible.

On this page: Medicine supply and limits | Warnings and actions against illegal advertising | Hand sanitisers and disinfectants | Supply of medical devices, including protective equipment and COVID-19 tests | Regulatory decisions | Safety advisories and updates | Further information

Medicine supply and limits

• <u>COVID-19 limits on dispensing and sales at pharmacies (//www.tga.gov.au/media-release/covid-19-limits-dispensing-and-sales-pharmacies)</u> (for consumers)

19 March 2020

Information for consumers about the limits imposed on the supply of some medicines and medical devices to ensure access for those who need them, including the list of affected products.

• <u>Limits on dispensing and sales of prescription and over-the-counter medicines</u> (//www.tga.gov.au/media-release/limits-dispensing-and-sales-prescription-and-over-counter-medicines) (for health professionals)

19 March 2020

Information for health professionals about the limits imposed on the supply of some medicines and medical devices, including the list of affected products.

• <u>TGA response to coronavirus (COVID-19) (//www.tga.gov.au/media-release/tga-response-coronavirus-covid-19)</u>

19 March 2020

Information on advertising of products related to COVID-19, GMP information for sponsors and

manufacturers and access to coronavirus tests, medicines and vaccines, including medicine shortages.

• <u>TGA cautions against over-buying medicines (//www.tga.gov.au/media-release/tga-cautions-against-over-buying-medicines)</u>

16 March 2020

The TGA's response to reports of local-level out-of-stocks in some pharmacies due to over-buying.

Warnings and actions against illegal advertising

• <u>Warning to consumers and advertisers about COVID-19 testing (//www.tga.gov.au/media-release/warning-consumers-and-advertisers-about-covid-19-test-kits)</u>

1 April 2020

COVID-19 tests must be done under the direction of a health professional. The advertising and sale of home tests is prohibited.

Oxymed Australia Pty Ltd fined \$63,000 for alleged advertising breaches
 (//www.tga.gov.au/media-release/oxymed-australia-pty-ltd-fined-63000-alleged-advertising-breaches)

27 March 2020

The alleged contraventions relate to the advertising of hyperbaric oxygen therapy chambers, not included in the ARTG.

<u>TGA issues warning about illegal advertising relating to COVID-19</u>
 (//www.tga.gov.au/media-release/tga-issues-warning-about-illegal-advertising-relating-covid-19)

24 March 2020

The TGA will take action in relation to the illegal advertising of therapeutic goods, including those that make false and misleading claims about preventing or curing COVID-19.

• <u>Warning about products claiming to treat or prevent the novel coronavirus</u>

(//www.tga.gov.au/media-release/warning-about-products-claiming-treat-or-prevent-novelcoronavirus)

7 February 2020

Information for advertisers and consumers relating to ads for therapeutic goods that claim to treat or prevent COVID-19, including specific advertising requirements and consequences for non-compliance.

Hand sanitisers and disinfectants

<u>Advertising claims and hand sanitisers (//www.tga.gov.au/covid-19-update-advertising-claims-and-hand-sanitisers)</u>

30 March 2020

A reminder that sponsors cannot make therapeutic use claims that refer to COVID-19.

Hand sanitisers and COVID-19 (//www.tga.gov.au/hand-sanitisers-and-covid-19)

29 March 2020

Information for sponsors, manufacturers and consumers on the appropriate use of hand sanitisers, how they are regulated in Australia and how to supply them.

• Regulation of disinfectants: Information for sponsors and manufacturers (//www.tga.gov.au/regulation-cleaners-and-disinfectants-information-sponsors-and-manufacturers)

27 March 2020

There is significant interest from potential sponsors and manufacturers to understand how disinfectants are regulated and how to supply them.

• <u>Appropriate use of disinfectants: Information for consumers, health professionals and healthcare facilities (//www.tga.gov.au/appropriate-use-disinfectants-information-consumers-health-professionals-and-healthcare-facilities)</u>

27 March 2020

We have identified disinfectants as being critical in preventing the spread of COVID-19. This information provides advice on how to use disinfectants properly.

20 March 2020

For sponsors and manufacturers wishing to make label claims of efficacy against COVID-19 for products that are either hard surface disinfectants or disinfectants that are medical devices.

Supply of medical devices, including protective equipment and COVID-19 tests

<u>COVID-19 test kits included on the ARTG for legal supply in Australia</u>
 (//www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia)

2 April 2020

A list of tests approved for inclusion on the Australian Register of Therapeutic Goods (ARTG).

<u>Expedited COVID-19 medical device application process (//www.tga.gov.au/expedited-covid-19-medical-device-application-process)</u>

31 March 2020

All applications in relation to COVID-19 are being expedited as a matter of priority (separate to the Priority Review pathway).

• Legal supply of COVID-19 test kits (//www.tga.gov.au/legal-supply-covid-19-test-kits)

30 March 2020

This is current advice relating to the supply of in vitro diagnostic medical devices for the detection of COVID-19/SARS-CoV-2 infections.

• <u>COVID-19 advice on surgical masks and gowns (//www.tga.gov.au/media-release/covid-19-advice-surgical-masks-and-gowns)</u>

23 March 2020

Information relating to surgical masks and gowns to assist healthcare organisations as they update their operating procedures during the outbreak.

• <u>Supplying COVID-19 tests (//www.tga.gov.au/media-release/supplying-covid-19-tests)</u>

20 March 2020

Information for sponsors regarding the supply of COVID-19 tests, including advice for those sponsors new to therapeutic goods regulation in Australia.

Regulatory decisions

• <u>Physical samples for batch release not required: a reminder for sponsors of biosimilars and biological medicines (//www.tga.gov.au/physical-samples-batch-release-not-required-reminder-sponsors-biosimilars-and-biological-medicines)</u>

27 March 2020

A change in process to facilitate batch release of biological medicines during the COVID-19 pandemic.

<u>Public notice of an amendment to the current Poison Standard</u>
 (//www.tga.gov.au/scheduling-decision-final/notice-amendment-current-poisons-standard-under-paragraph-52d2a-therapeutic-goods-act-1989)

24 March 2020

Amendments in relation to hydroxychloroquine and salbutamol.

• <u>Exemption for coronavirus (COVID-19) medical devices (//www.tga.gov.au/exemption-coronavirus-covid-19-medical-devices)</u>

24 March 2020

Announcement that certain medical devices for the diagnosis and treatment of COVID-19 will be exempt from various provisions of the therapeutic goods act to facilitate necessary access.

• <u>TGA suspends overseas GMP inspections and QMS audits until further notice</u> (//www.tga.gov.au/media-release/tga-suspends-overseas-gmp-inspections-and-qms-audits-until-further-notice)

19 March 2020

Information for manufacturers of therapeutic goods about the suspension of all overseas GMP (Good Manufacturing Practice) inspections and QMS (Quality Management System) audits.

Safety advisories and updates

• <u>Clinical trial processes (//www.tga.gov.au/clinical-trial-processes)</u>

31 March 2020

Clarification about the clinical trial process as it relates to COVID-19.

• <u>No evidence to support intravenous high-dose vitamin C in the management of COVID-19 (//www.tga.gov.au/alert/no-evidence-support-intravenous-high-dose-vitamin-c-management-covid-19)</u>

27 March 2020

We have investigated a report that intravenous high-dose vitamin C may be beneficial in the management of COVID-19.

How COVID-19 testing works (//www.tga.gov.au/how-testing-works-covid-19)

27 March 2020

Information for consumers on how we test for COVID-19 in Australia.

<u>COVID-19 testing in Australia: information for health professionals</u>
 (//www.tga.gov.au/covid-19-testing-australia-information-health-professionals)

27 March 2020

Information on the two types of COVID-19 tests (nucleic acid/PCR and serology antibody tests), including test performance.

• <u>COVID-19 information for clinicians on ventilators and alternative strategies when in short supply (//www.tga.gov.au/covid-19-information-clinicians-ventilators-and-alternative-strategies-when-short-supply)</u>

26 March 2020

The TGA has been involved in exploring ways to further increase supply of ventilators when and where they are needed.

New restrictions on prescribing hydroxychloroquine for COVID-19
 (//www.tga.gov.au/alert/new-restrictions-prescribing-hydroxychloroquine-covid-19)

24 March 2020

Only certain types of specialists will be able to prescribe hydroxychloroquine to new patients.

No evidence to support claims ibuprofen worsens COVID-19 symptoms
 (//www.tga.gov.au/alert/no-evidence-support-claims-ibuprofen-worsens-covid-19-symptoms)
 20 March 2020

Clarifying there is currently no evidence to support a link between ibuprofen and worsening COVID-19 symptoms.

Further information

If you have further questions about medicines and medical devices relating to COVID-19, you can contact the TGA Info line on 1800 020 653.

Please bear with us as we work through high call volumes.

You may also choose to subscribe to the <u>TGA Update email list (//www.tga.gov.au/tga-update-email-list)</u> for same-day notifications of new media releases, and follow the <u>TGA Facebook</u> (https://www.facebook.com/TGAgovau/), <a href="https://www.linkedin.com/company/therapeutic-goods-to-g

<u>administration/</u>), <u>Twitter (https://twitter.com/TGAgovau/)</u> and <u>Instagram</u> (<u>https://www.instagram.com/tgagovau/</u>) pages for timely information and announcements related to COVID-19.

For information and advice about the virus that is not specific to therapeutic goods, visit the <u>Department of Health's daily health alert regarding COVID-19 (https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert).</u>

Category: Therapeutic Goods Administration (TGA)

URL: https://www.tga.gov.au/node/904116 (https://www.tga.gov.au/node/904116)