

## Australia and New Zealand Legal and Regulatory Affairs

### Watchdog Update



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### TGA

#### Efforts to support health system COVID-19 responses

The TGA has published the list of COVID-19 test kits included on the Australian Register of Therapeutic Goods (ARTG) for legal supply in Australia [1]. It is collaborating widely to help ensure the supply of ventilators [2] and undertaking an expedited assessment process for all medical devices associated with the detection, prevention and treatment of COVID-19 [3]. It has published information regarding testing for COVID-19 in Australia [4, 5], disinfectants [6], surrogate viruses for use in testing disinfectants [7], ventilators [8], surgical masks and gowns [9] and clinical trial processes related to COVID-19 [10]. It has placed new restrictions on prescribing hydroxychloroquine for COVID-19 to prevent a potential shortage of this product in Australia and serious risks to patients [11] and it has released the influenza vaccines for the 2020 season [12].

#### Efforts particularly relevant to cell and gene therapy

The TGA has reminded sponsors of biological medicines and biosimilars that, to facilitate batch release of biological medicines during the COVID-19 pandemic, physical samples are not required for batch release until further notice [13]. In line with Australian Government travel restrictions, it has also suspended overseas GMP inspections and QMS audits [14].

### Advertising

The TGA continues to work to prevent illegal advertising. It has issued warnings about illegal advertising relating to COVID-19 [15], that the advertising and supply of self-tests for serious infectious diseases, such as COVID-19, is prohibited under therapeutic goods legislation and that testing for COVID-19 should only be conducted in an accredited pathology laboratory, or by a healthcare professional at the point of care [16]. It has issued Oxymed Australia Pty Ltd infringement notices for alleged advertising breaches relating to the advertising of hyperbaric oxygen therapy chambers not included in the ARTG. The advertisements for hyperbaric oxygen therapy chambers made therapeutic claims to treat serious ailments, diseases and conditions and included representations in relation to Coronavirus (COVID-19) [17]. It has also issued ATP Science Pty Ltd (ATP Science) infringement notices for the alleged advertising of a number of therapeutic goods not included in the ARTG. The TGA alleges that ATP Science made a number of claims in relation to the goods, including prohibited representations relating to cancer and the treatment of mental health conditions [18]. The Secretary of the Department of Health has commenced proceedings in the Federal Court of Australia against Evolution Supplements Australia Pty Ltd for alleged advertising of therapeutic goods not entered in the ARTG. Advertising by Evolution Supplements Australia is alleged to have included references to Selective Androgen Receptor Modulators (SARMs). SARMs are experimental medicines and no

SARM has been fully researched, or approved for human use. The use of SARMS has been linked to liver failure and increased risk of heart attack and stroke. Importing, supplying or possessing SARMS without a valid prescription, license or authority is illegal. [19]

## OGTR

The Office of the Gene Technology Regulator (OGTR) has provided organisations with advice about how they can continue to comply with OGTR facility certification guidelines and OGTR licence conditions in an environment where key staff are no longer in their physical workplace and common laboratory consumables are in limited supply. The advice relates to anticipating issues and putting in place mitigation strategies in advance [20, 21].

## OTHER NEWS

The Clinical Trials Project Reference Group (CTPRG) has provided advice to institutions, Human Research Ethics Committees (HRECs), researchers and sponsors involved in clinical research in the context of the COVID-19 pandemic [22]. The CTPRG, formerly the Clinical Trials Jurisdictional Working Group (CTJWG), was established in July 2014 and involves senior officials from Commonwealth, State and Territory health departments, and the National Health and Medical Research Council (NHMRC).

The NHMRC has also provided information relevant to research to address the COVID-19 pandemic and its consequences [23].

The Medical Journal of Australia has published 'Managing haematology and oncology patients during the COVID-19 pandemic: interim consensus guidance' as a Preprint article [24].

[1] COVID-19 test kits included on the ARTG for legal supply in Australia, <https://www.tga.gov.au/covid-19-test-kits-included-artg-legal-supply-australia>, published on 4 April 2020

[2] TGA collaborating to help ensure the supply of ventilators, <https://www.tga.gov.au/tga-collaborating-help-ensure-supply-ventilators>, published on 2 April 2020

[3] Expedited COVID-19 medical device application process, <https://www.tga.gov.au/expedited-covid-19-medical-device-application-process>, published on 31 March 2020

[4] How testing works for COVID-19, <https://www.tga.gov.au/how-testing-works-covid-19>, published on 27 March 2020

[5] COVID-19 testing in Australia - information for health professionals, <https://www.tga.gov.au/covid-19-testing-australia-information-health-professionals>, published on 27 March 2020

[6] Appropriate use of disinfectants: Information for consumers, health professionals and healthcare facilities, <https://www.tga.gov.au/appropriate-use-disinfectants-information-consumers-health-professionals-and-healthcare-facilities>, published on 27 March 2020

- [7] Surrogate viruses for use in disinfectant efficacy tests to justify claims against COVID-19, <https://www.tga.gov.au/surrogate-viruses-use-disinfectant-efficacy-tests-justify-claims-against-covid-19>, published on 20 March 2020
- [8] COVID-19 information for clinicians on ventilators and alternative strategies when in short supply, <https://www.tga.gov.au/covid-19-information-clinicians-ventilators-and-alternative-strategies-when-short-supply>, published on 26 March 2020
- [9] COVID-19 advice on surgical masks and gowns, <https://www.tga.gov.au/media-release/covid-19-advice-surgical-masks-and-gowns>, published on 23 March 2020
- [10] Clinical trial processes - Information relating to COVID-19, <https://www.tga.gov.au/clinical-trial-processes>, published on 31 March 2020
- [11] New restrictions on prescribing hydroxychloroquine for COVID-19, <https://www.tga.gov.au/alert/new-restrictions-prescribing-hydroxychloroquine-covid-19>, published on 24 March 2020
- [12] Influenza vaccines released for 2020 season, <https://www.tga.gov.au/behind-news/influenza-vaccines-released-2020-season>, published on 1 April 2020
- [13] Physical samples for batch release not required: a reminder for sponsors of biosimilars and biological medicines, <https://www.tga.gov.au/physical-samples-batch-release-not-required-reminder-sponsors-biosimilars-and-biological-medicines>, published on 27 March 2020
- [14] TGA suspends overseas GMP inspections and QMS audits until further notice, <https://www.tga.gov.au/media-release/tga-suspends-overseas-gmp-inspections-and-qms-audits-until-further-notice>, published on 19 March 2020
- [15] TGA issues warning about illegal advertising relating to COVID-19, <https://www.tga.gov.au/media-release/tga-issues-warning-about-illegal-advertising-relating-covid-19>, published on 24 March 2020
- [16] Warning to consumers and advertisers about COVID-19 test kits, <https://www.tga.gov.au/media-release/warning-consumers-and-advertisers-about-covid-19-test-kits>, published on 1 April 2020
- [17] Oxymed Australia Pty Ltd fined \$63,000 for alleged advertising breaches, <https://www.tga.gov.au/media-release/oxymed-australia-pty-ltd-fined-63000-alleged-advertising-breaches>, published on 27 March 2020
- [18] ATP Science issued infringement notices for \$302,400 for alleged advertising breaches, <https://www.tga.gov.au/media-release/atp-science-issued-infringement-notices-302400-alleged-advertising-breaches>, published on 3 April 2020
- [19] Court proceedings commenced against Evolution Supplements Australia and its sole director for alleged advertising breaches, <https://www.tga.gov.au/media-release/court-proceedings-commenced-against-evolution-supplements-australia-and-its-sole-director-alleged-advertising-breaches>, published on 13 March 2020
- [20] OGTR COVID-19 Update, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/covid-19>, published on 26 March 2020

[21] Advice from the OGTR on managing certified facilities and licences during COVID-19 restrictions, 01 April 2020

[22] Clinical Trials, <https://www1.health.gov.au/internet/main/publishing.nsf/Content/Clinical-Trials>, updated 27 march 2020

[23] The National Health and Medical Research Council (NHMRC) is committed to supporting national and international efforts, including NHMRC funded experts, to address the COVID-19 pandemic and its consequences, <https://www.nhmrc.gov.au/research-policy/COVID-19-impacts>, accessed 5 April 2020

[24] Managing haematology and oncology patients during the COVID-19 pandemic: interim consensus guidance, <https://www.mja.com.au/journal/2020/212/10/managing-haematology-and-oncology-patients-during-covid-19-pandemic-interim>, accessed 8 April 2020