



# TGA Advice on the regulation and use of personal protective equipment (PPE), including masks

Below is the response from the Therapeutic Goods Administration from the Extraordinary NCTF and TFIWG COVID-19 teleconference held on 25 March 2020 on approval requirements for medical equipment (PPE, Masks etc) and medical consumables. Members reported concerns that TGA required containers to be approved and retail containers and products must match.

## **Hand sanitiser:**

[www.tga.gov.au/hand-sanitisers-and-covid-19](http://www.tga.gov.au/hand-sanitisers-and-covid-19) - Outlines the requirements for the three classes of hand sanitiser:

- general consumer goods (for personal or domestic use, without specific claims, etc)
- hand sanitisers regulated by TGA (claiming to kill specific organisms, and/or for use in clinics and hospitals)
- specific formulations excluded from TGA regulation for the duration of the COVID-19 pandemic (limited ingredients and strict labelling requirements)

Additional information has also been published clarifying advertising claims, including in the context of the exemption - [www.tga.gov.au/covid-19-update-advertising-claims-and-hand-sanitisers](http://www.tga.gov.au/covid-19-update-advertising-claims-and-hand-sanitisers)

**Masks:** A range of advice on the regulation and use of personal protective equipment (PPE), including masks, has been provided:

- ***Regulation of Personal Protective Equipment and COVID-19*** - [www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19](http://www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19) - outlining that most PPE is exempt from TGA regulation, but where PPE is intended for therapeutic use it needs to be included in the Australian Register of Therapeutic Goods (ARTG) at the appropriate classification prior to import, supply, export or advertising. This page includes information on the manufacturer and supply of PPE in Australia, applicable standards, and a description of various sorts of face masks as well as gowns, goggles and visors.
- ***Advice on surgical masks and gowns during COVID-19*** - [www.tga.gov.au/media-release/advice-surgical-masks-and-gowns-during-covid-19](http://www.tga.gov.au/media-release/advice-surgical-masks-and-gowns-during-covid-19) - provides information for health professionals on procurement and use of PPE during the COVID-19 pandemic
- ***Reuse of face masks and gowns during the COVID-19 pandemic*** - [www.tga.gov.au/behind-news/reuse-face-masks-and-gowns-during-covid-19-pandemic](http://www.tga.gov.au/behind-news/reuse-face-masks-and-gowns-during-covid-19-pandemic) - outlining how reprocessing of PPE might be undertaken and associated regulatory requirements.

The material recently published by TGA also includes information on a range of other COVID-19 related issues, and is indexed at [www.tga.gov.au/collection/covid-19](http://www.tga.gov.au/collection/covid-19)

In terms of regulatory compliance, except where exemptions have been put in place, normal regulatory requirements apply. While TGA has not relaxed normal regulatory requirements which apply, any applications received for COVID-19 relevant products are being prioritised. This includes GMP requirements for medicines (such as regulated hand sanitisers), and conformity assessment requirements for medical devices.

**Comparable overseas regulators:** We also spoke about our comparable overseas regulatory arrangements for medical devices (noting this does not apply for hand sanitisers, which are regulated under the medicines framework). The TGA has long accepted certification from European notified bodies as evidence of compliance with the conformity assessment procedures, in addition to the conformity assessment certificates issued by the TGA.

Since October 2018, comparable overseas regulators and assessment bodies include the US FDA, Health Canada and Japanese regulators

The details of what evidence (certificates, documents etc) from comparable overseas regulators can be used is outlined in guidance on the TGA website: [www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds](http://www.tga.gov.au/publication/use-market-authorisation-evidence-comparable-overseas-regulators-assessment-bodies-medical-devices-including-ivds).

Table 2 in particular outlines what documents must be included with the application for inclusion for each device classification. It should be noted that this is evidence to support the application for inclusion on the ARTG, and is still subject to TGA assessment and decision. For many applications this will be completed within 20 working days (and as mentioned above we are prioritising COVID-19 related applications) but these applications may be selected for audit and further information requested (audit being mandatory for a range of high risk devices).