Face masks and COVID-19 - 9 November 2022

The Therapeutic Goods Administration (TGA) publishes information and resources about face masks for consumers, health professionals and industry. This page compiles all of our resources related to face masks and COVID-19.

For other COVID-19 information from the TGA, see Coronavirus (COVID-19): Information on medicines and medical devices.

Overview

A face mask meets the definition of a medical device when the following claims are made:

- the face mask is to be used for the prevention of the transmission of disease between people, or
- the face mask is intended for therapeutic use such as for surgical, clinical, medical use, or use in other health services.

If the manufacturer's labelling, advertising, or documentation contain the claims above, the face mask is considered to be a medical device and is required to be included in the Australian Register of Therapeutic Goods (ARTG).

Face masks that are medical devices, and are non-sterile, are regulated as Class I medical devices, which is the classification for low risk devices. However, the TGA has put in place more rigour and validation process for face masks included in the ARTG, including an audit of the evidence held by the manufacturer to demonstrate the performance and the quality of the face masks. Further information can be found here:

- Evidence requirements for face masks that are medical devices

The following resources provide an overview of the regulatory requirements for face masks in Australia:

- Face masks and respirators that are regulated by the TGA
- Regulation of Personal Protective Equipment and COVID-19

This video provides manufacturers and suppliers technical information on face masks and respirators that are regulated as medical devices.

Safety alerts for face masks

The TGA has issued the following safety alerts related to face masks:

- Use of face masks during MRI examinations

For all safety alerts issued by the TGA see Safety information.

Post-market review of face masks

The TGA is undertaking a post-market review of face masks included in the ARTG. For information related to this review, see:

- Post-market review of face masks: Overview
- Post-market review of face masks: Cancelled ARTG entries
- Post-market review of face masks: Non-compliance notices
- Post-market review of face masks: Outcomes and actions

- Testing results of face masks and respirators: TGA Laboratories testing report
- For information about all other TGA compliance actions related to face masks, see Compliance actions and outcomes, Media releases & statements and Medical devices and IVDs: Cancellations from the ARTG.

Importing, supplying, or manufacturing face masks

The following resources are intended to help importers, suppliers, and manufacturers of face masks to understand their regulatory obligations.

- Regulation of Personal Protective Equipment and COVID-19
- Face masks and respirators that are regulated by the TGA
- Guidance on medical/surgical face masks and respirator standards - key performance aspects.
- Evidence requirements for face masks that are medical devices
- Importing personal protective equipment into Australia during the COVID-19 pandemic
- Manufacturing medical devices for COVID-19 including 3-D printing

Using face masks in healthcare settings

The following resources provide guidance to healthcare professionals on the use of face masks.

- Advice on face masks and gowns during COVID-19
- Reuse of face masks and gowns during the COVID-19 pandemic.

Face masks and COVID-19 - 21 June 2020

Current page https://www.tga.gov.au/resources/explore-topic/covid-19/covid-19-personal-protective-equipment-ppe/face-masks-and-covid-19

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Guidance on medical/surgical face masks and respirator standards – key performance aspects

Version 3.1, October 2021

Contents

The TGA is currently undertaking a post-market review of face masks included in the Australian Register of Therapeutic Goods (ARTG). The TGA is aware there are many different standards available to manufacturers; and we are familiar with differences between these standards. The TGA has also identified common areas of non-compliance against claimed standards throughout this review process. This Guidance intends to assist manufacturers in choosing appropriate standards and to set out the TGA's expectations for performance testing of respirators, surgical respirators and medical/surgical facemasks, before inclusion on the ARTG.

The information provided may be useful to manufacturers and sponsors, as well as health care facilities and health care personnel. This information is not exhaustive and not designed to be a checklist for compliance with the Essential Principles. This guidance will be updated periodically to provide further clarity for both manufacturers and sponsors.

More information on regulation of PPE and different types of masks and respirators is provided at Regulation of Personal Protective Equipment and COVID-19.

A summary of some of this information is available in a guidance video on face masks:

https://www.youtube.com/watch?v=kngngfkS17E

Background

Face masks meet the definition of a medical device when the following claims are made:

- The face mask is to be used for the prevention of the transmission of disease between people, or
- The face mask is suitable for therapeutic use such as for surgical, clinical, medical use, or use in other health services.

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All classes of medical devices need conformity assessment evidence before they can be manufactured and supplied. Conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device (including IVD medical devices) complies with the Essential Principles. These Principles relate to safety and performance aspects of the device including its design and construction. Demonstrating compliance with them establishes that the product is safe and fit for its intended purpose. The manufacturer should maintain an active and robust quality management system (QMS) and the application of sound manufacturing practices for evaluating risk and in the design and construction of medical devices.

The intended purpose needs to suitable for the device and it must perform in the way intended by the manufacturer. (See Annex 1 for table of appropriate GMDN codes for masks and respirators and Face masks and respirators that are regulated by the TGA for further TGA advice on regulation of face masks).

Manufacturers of all medical devices (including IVD medical devices) manufactured and/or supplied in Australia should ensure they have:

- appropriate conformity assessment procedures in place for the device; and
- appropriate documentation demonstrating compliance of the device with the Essential Principles.

Compliance with the Essential Principles can be demonstrated by showing that your product meets an applicable standard.

Note

Although the use of standards to demonstrate compliance with the Essential Principles is not mandated under the Regulations, the TGA recognises certain standards to assist manufacturers in complying with the conformity assessment procedures and the Essential Principles.

Standards

A range of standards may be of assistance to manufacturers of respirators surgical respirators and medical/surgical masks, including:

- Standards that can be applied broadly for any medical device
- Standards related to performance specifications of certain types of devices/products
- Standards, sub-parts of standards and published procedures related to the application of a specific test methods to evaluate specific performance criteria

When choosing which standards to apply to each device, manufacturers should take into consideration the:

- intended purpose of the device
- environment in which it is likely to be used
- likely users of the device; and
- generally acknowledged state-of-the-art; or the level of development reached at any particular time usually as a result of modern methods.

Table 1 below identifies a non-exhaustive list of standards that may be considered by the manufacturers when determining how to minimise risk associated with the device and demonstrate compliance with the conformity assessment procedures and the Essential Principles. A device should only claim compliance with a standard if it meets all the applicable clauses based on the device design and the intended purpose.

Table 1 highlights certain standard clauses that are of particular importance for respirators and surgical/medical face masks to effectively prevent disease transmission in a medical setting. The listed performance parameters have also been identified as common causes of non-compliance in regulatory surveillance. For Australian manufacturers, NATA accredited laboratories may provide testing services to evaluate your product against the referenced standard clauses. Again, these performance aspects are non-exhaustive and evidence needs to be provided to support any additional performance claims.

Note

It is preferable that any evidence submitted, be from a laboratory holding accreditation from NATA (or equivalent accreditation issued by an ILAC certified body) **for the test(s) applied**. If evidence from a non accredited laboratory is submitted, this may not be considered acceptable evidence, unless other information can be provided to support the reliability of the

analysis (e.g. SOPs, method validation and raw data from the testing laboratory for the tests applied).

In some cases the TGA may require you to provide specific technical details in relation to how testing has been conducted to support any test reports or certificates submitted (including from an accredited laboratory). Technical information required may include (but is not limited to) the standard operating procedures (SOPs), work-instructions, testing worksheets/records, photographs of the samples tested, method validation reports, calibration records, or details of equipment used by the test laboratory.

Table 1 General guidance on Standards for different types of face masks and respirators

Product type	Typical intended purpose(s)	Important performance parameters	Standards, sub-parts of standards, procedures and requirements
Any Medical Device	Quality management systems	Systems to demonstrate an organizations ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.	ISO 13485:2016 ISO 9001:2015
Any Medical Device	Application of risk management	Processes for a manufacturer to identify the hazards associated with a medical device to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.	ISO 14971:2019
All Medical Devices	Labelling	Sufficient and accurate information to be provided with the medical device	Therapeutic Goods (Medical Devices) Regulations 2002 – Schedule 1 – Section 13 – Information to be provided with medical devices
Devices in Contact with Skin	Biocompatibility	Biological Evaluation of Medical Devices and testing within a risk management framework.	ISO10993-1:2018
		Tests for *in vitro* cytotoxicity, designed to determine the biological response of mammalian cells *in vitro* to a device and or extracts of a device.	ISO 10993-5:2009

Product type	Typical intended purpose(s)	Important performance parameters	Standards, sub-parts of standards, procedures and requirements
		Assessment of medical devices and their constituent materials with regard to their potential to produce irritation and skin sensitisation.	ISO 10993-10:2010
Surgical / Medical Face Mask	Requirements for single use medical masks intended to provide barrier protection between the mouth and nose of the wearer and immediate environment	General requirements and classifications	AS 4381:2015 EN 14683:2019 ASTM F2100-20 YY 0469-2011
		Fluid resistance	ISO 22609:2004 ASTM F1862/F1862M-17
		Bacterial filtration efficiency	ASTM F2101-19 EN 14683:2019 Annex B
		Breathability	EN 14683:2019 Annex C
Respirator	Requirements for respirators intended to provide protection against airborne particles	General requirements and classifications	AS/NZS 1716:2012 (P2/P3 classes) 42 CFR 84 (N-, R- and P-classification at 95, 99 and 99.9% filter efficiency) EN 149:2001 + A1:2009 (FFP2/FFP3 classes) GB2626: 2019 (KN and KP 95/100 classes) ISO 16900 / 17420
		Particulate filtration efficiency	AS/NZS 1716:2012 Appendix I NIOSH TEB-APR-STP-0059 (N95) EN 13274-7:2019

Product type	Typical intended purpose(s)	Important performance parameters	Standards, sub-parts of standards, procedures and requirements
		Breathability	AS/NZS 1716:2012 Appendix G NIOSH TEB-APR-STP-0003 NIOSH TEB-APR-STP-0007 EN 149:2001 + A1:2009 Clause 8.9 GB 2626: 2019 Clause 6.5 and 6.6
		Fit (Leakage)	AS/NZS 1716:2012 Appendix D EN 149:2001 + A1:2009 Clause 8.5 GB 2626: 2019 Clause 6.4
		Head strap and head harness	The breaking strength of each head strap shall be at least 10 N.
Surgical Respirator / Medical Protective Mask	Requirements for surgical respirators intended to provide protection against airborne particles and fluid resistance	Surgical respirators should comply with performance requirements of relevant respirator standards, and also demonstrate the appropriate level of fluid resistance like surgical masks.	GB 19083:2010 AS/NZS 1716:2012 42 CFR 84 EN 149:2001 + A1:2009 GB2626: 2019 ISO 22609:2004 ASTM F1862/F1862M-17 ISO 16900 / 17420 Exhalation valve is not acceptable in surgical respirators due to unfiltered exhaled air.

Note

Standards Australia is adopting ISO 16900 to transition away from AS/NZS 1716:2012. Manufacturers are encouraged to keep informed of changes to relevant standards. Typically, application of a currently adopted standard is considered a minimum benchmark for applying solutions having regard to the generally acknowledged state of the art. Application of superseded standards is generally no acceptable. Manufacturers should consider how they will transition standards as they change and consider risk management activities such as a gap analysis to understand any potential impacts.

Application of testing methods

When considering application of testing methods to assess the performance of medical devices, there are a number of elements manufacturers should consider in order to determine what methods should be applied, and how they should be applied. This typically includes:

- The intended purpose of the device;
- The design of the device, taking into consideration
  - materials, construction, and manufacturing processes
  - if different parts of the device relate to different functions that contribute to achieving the intended purpose;
- The results of any design calculations, risk analysis, investigations, technical tests, or any other tests carried out in relation to the device;
- Post-market monitoring of the device.

Sampling plans

A systematic and periodic testing schedule is essential in ensuring consistent and adequate product quality of medical devices. A proper sampling plan is critical to ensure the sample results are reflective of the quality of the device group which the samples are drawn from. The sampling plan is a combination of the sample size and the acceptability criteria. It should be determined based on appropriate risk assessments and sound statistical methods. Testing should be an ongoing part of the manufacturer's technical documentation and triggered as specified by the manufacturer's quality management procedure, such as when changes are made to the design, product specifications, productions methods, suppliers or raw materials of the product. Some of the respirator and medical mask standards prescribe the sampling plan or the sample size requirements for specific tests. However, it should be recognised that:

1. There are noted differences between the sampling requirements of different standards for similar tests.
2. It may not be adequate to test to the selected standards without understanding the context of the sampling plan or without appropriate risk assessments.
3. It may be insufficient to only present test results of isolated, limited lots, especially without demonstration of adequate quality management systems.

For medical/surgical facemasks, the TGA expects manufacturers to make available test evidence of conformity for fluid resistance, bacterial filtration efficiency and breathability:

1. To the acceptable quality limit (AQL) of 4.0% and the general inspection level II.
2. On three non-consecutive lots or justification to demonstrate that lot to lot variability in performance is acceptable.

An AQL of 4.0% is referenced by multiple relevant standards, including ASTM F2100-20, ISO 22609:2004, and ASTM F1862/F1862M-17. Examples of acceptable sampling plans can be found in ISO 2859-1:1999 or ASQ/ANSI Z1.4. Sampling plans should be established with consideration to the inspection level, lot size and AQL and known manufacturer tolerances and quality. The TGA recommends general inspection level II unless otherwise statistically justified.

Note: Specifically for the fluid resistance, both ISO22609:2004 and ASTM F1862/F1862M-17 require

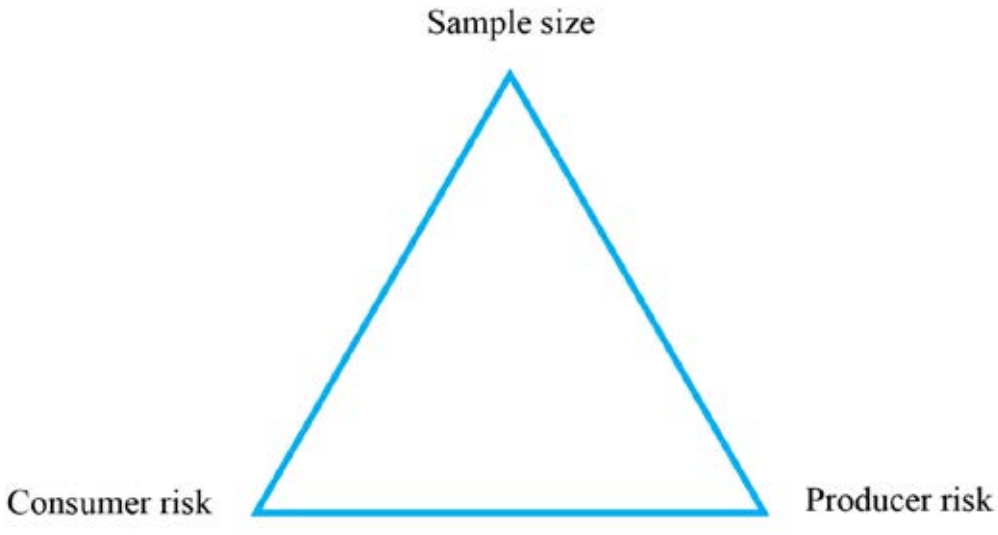
1. At minimum 32 samples to be tested per test
2. Masks to meet an AQL of 4%

The TGA requires both these conditions to be met, that is a minimum of 32 masks tested per batch, and each batch tested to be accepted by a sampling plan to AQL 4%, General Inspection level II (or a plan providing comparable Consumer Risk Quality levels as described below), dependant on your batch size and manufacturing quality output. This means that for lot sizes greater than 280, a sample size greater than 32 is required to demonstrate an AQL 4.0% at General Inspection Level II, Normal Inspection.

The YY 0469:2011 and EN 14683:2019 (optionally) require a sampling size of 3-5 units depending on the tests applied. Such limited sample size is deemed **insufficient** to demonstrate safety, consistency and quality of the device and therefore not recommended.

When formulating a sampling plan, it is impossible to achieve all three options of minimising the sample size, minimising the consumer risk (failure to detect a performance issue) and minimising producer risk (rejecting acceptable product lot). For a large lot size, a single sampling plan to the AQL of 4%, General Inspection Level II requires a considerable amount of samples to be tested. To reduce the burden of large testing regimes while still ensuring sufficient consumer protection, manufactures may consult the operating characteristic (OC) curves in the

ISO 2859-1:1999 and derive appropriate sampling plans which achieve an acceptable risk to the consumer comparable to the AQL of 4%, General Inspection Level II. Such customised sampling plans may require smaller sample size but incur higher risk to the producer. It is a trade-off that the manufacturers can choose between.



ISO 2859-1:1999 is designed for continuing series of lots, under a controlled manufacturing process which should account for switching rules. Thus, the manufacturers should apply relevant tests to successive lots and switch between normal/tightened/reduced inspections based on the results. To demonstrate performance specifications are maintained across production lots.

Example of AQL OC Curve Implementation

A manufacturer is producing batches of surgical masks greater than 35,000, and wants to test fluid resistance to an AQL of 4%, General Inspection Level II, Normal Inspection. The appropriate single sampling plan defined in ISO 2859-1 or ASQ Z1.4 requires 315 items to be tested with a Pass/Fail criteria of 21/22. A Consumer Risk Quality (CRQ) of 8.84% is derived from this sampling plan (10% batch acceptance). The manufacturer decides that they want to reduce the requirement for testing fluid resistance on every batch, and decides to incorporate alternate samples methodologies that will lower the batch testing requirements, whilst ensuring that the equivalent CRQ remains the same or less. Below is a table of some of the sampling plans that may be available to a manufacturer in this scenario, noting that if a batch fails testing, then it will not be released.

Sampling Plan Type	Sampling Plan	Consumer Risk Quality	Sample Size	Pass/Fail Criteria
Single	AQL 4%, Code M	8.84%	315	21/22
	AQL 1,5%, Code J	8.16%	80	3/4
	AQL 0.4%, Code G	6.94%	32	0/1
	AQL 1%, Code H	7.56%	50	1/2
Double	AQL 4%, Code M	8.84%	200/200	9/14--23/24

Sampling Plan Type	Sampling Plan	Consumer Risk Quality	Sample Size	Pass/Fail Criteria
	AQL 1%, Code H	5.94%	32/32	0/2--1/2
Multiple	AQL 1%, Code H	5.85%	26/13/13/13	0/2--0/2--0/2--0/2--1/2

Respirator standards typically either do not specify sampling requirements or have not provided justifications for the sample size chosen.

For respirators and surgical respirators devices, the TGA requires manufacturers to provide test evidence of conformity on three non-consecutive lots. For the PFE test, the number of samples tested must be **at least 10** or the sample size requirement of the referenced standard (Table 2), **whichever is larger**.

Table 2 Common respirator Standards and sample size requirements for the PFE test

Standards (Common designation)	AS/NZS 1716:2012 (P2)	42 CFR 84 (N95)	EN 149:2001+A1:2009 (FFP2)	GB 2626:2019 (KN95)	GB 2626:2006 (KN95)	GB 19083: 2010
PFE testing sample size by the Standard	Unspecified	20	9	20	15	6

Manufacturers are encouraged to formulate the sampling plans for respirator related tests based on appropriate statistical methods, such as by consulting the OC curves in the ISO 2859-1:1999. The AQL should be determined based on risk assessments, but is recommended to be 4% or better given the AQL requirement for medical/surgical facemasks. Any customised sample plan should also not be in conflict with the requirements in the referenced standards.

TGA requirements for fluid resistance testing

Fluid droplets generated by coughing, sneezing or some medical procedures are widely acknowledged to be a source of pathogen transmission, including the COVID-19 virus[1,2,3]. To effectively prevent disease transmission through fluid droplets, facemasks must include a fluid resistant barrier. Fluid resistance will aid in preventing large droplets and splashes from reaching the mouth or nose, potentially transmitting the virus or other infectious agents. For this reason, the TGA requires face masks intended to be used in medical or surgical settings to be resistant to fluid penetration.

For masks regulated as medical devices that claim (or it is implied) to provide fluid resistance, including surgical respirators, the manufacturer should:

[1] https://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert/what-you-need-to-know-about-coronavirus-covid-19#how-it-spreads
[2] https://www.who.int/news-room/q-a-detail/q-a-how-is-covid-19-transmitted
[3] https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Spread

1. Identify all areas of the mask that are intended to provide a barrier to fluid penetration in the technical documentation for the device. Areas near or covering the mouth and nose must provide a barrier to fluid penetration.

2. Hold evidence that the device provides resistance to fluid penetration across all areas of the mask intended to do so.

Attention should be paid to areas of the mask where the material type or thickness differs from the main body material, and any seams located in the central area of the mask covering the nose and mouth

To note: not all respirators require compliance with luid resistance requirements, only surgical respirators

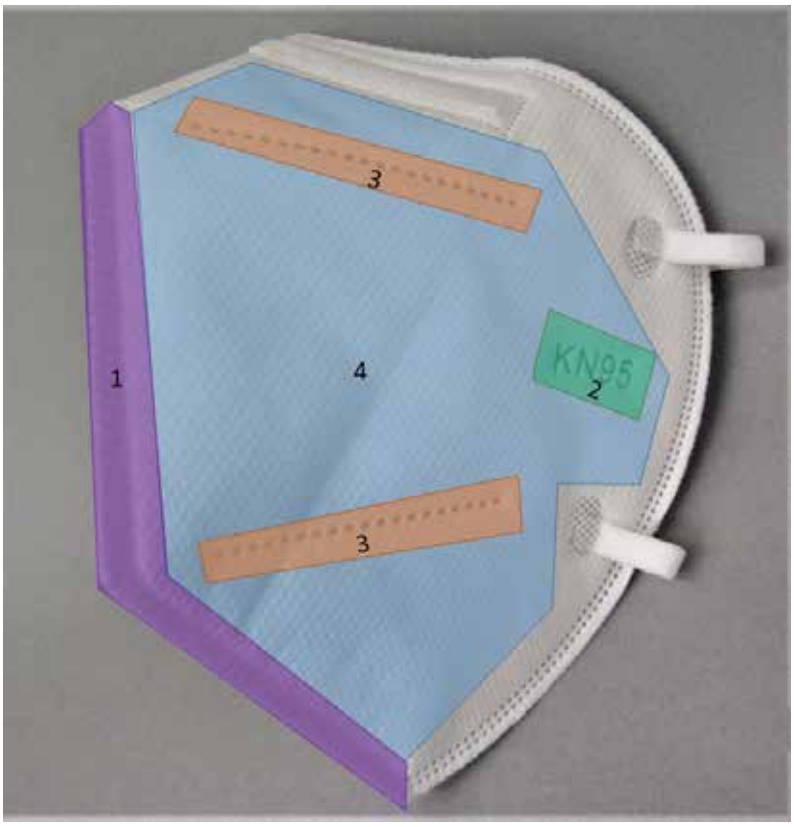


Figure 1 – Surgical respirator with 4 identified areas of difference that must be tested for fluid resistance.

For example, in Figure 1, this surgical respirator has a central seam (1, purple), embossed KN95 label (2, green) and embossed lines (3, orange) that are within the central area of the mask covering the nose and mouth. All three of these areas, in addition to the main body material (4, blue), would need to be tested for fluid resistance level.

Figure 2 – Main body (green) of the surgical/medical facemask must be tested for fluid resistance; the perimeter region (red) can be excluded from the testing.

For surgical/medical facemasks (Figure 2), the main body (green) is the functionally critical region and needs to be tested for fluid resistance level. The main body is considered uniform in terms of the structure and the material, and therefore is required to be tested once. Where there are areas of differing material type or thickness in the main body, such as logos, these also need be tested separately. The perimeter region (red) may be excluded from the fluid resistance testing.

Where standards such as ISO 22609 or ASTM F1862/FM1862M are being used to demonstrate compliance with the Essential Principles, the TGA would expect testing reports to include:

- Identification of all areas of the mask that were tested for fluid resistance.
- Information related to sample pre-treatment and testing methodology conducted by the testing laboratory.
- Selected blood pressures, volumes, and velocities of synthetic blood used
- The number of samples tested and numbers of pass/ failed samples.
- Information about the sampling plan used at each location.
- Any deviations from the requirements of the standard.

The TGA expects all areas of difference will be tested to at a minimum an AQL of 4.0%, General Inspection II. Each area challenged needs to meet the AQL requirement individually.

TGA Requirements for Sub-micron Particulate Filtration Efficiency (PFE)

Single Use Respirators are disposable devices made from multiple layers of non-woven polymers. They are expected to form a tight seal to a wearer's face. They are intended to protect the wearer from the transfer of microorganisms and airborne particulate materials while maintaining adequate breathability and comfort. Respirators are labelled with an effective particulate filtration efficiency for which they have been tested, to ensure they remove the minimum specified percentage of solid and/or liquid aerosols.

Particulate filtration efficiency testing assesses the ability of the mask to protect against infectious agents. It measures the ability of a respirator to filter out sub-micron sized, electrostatically neutral salt crystals from a stream of air penetrating the mask. Depending on the nominated standard, the expected filtration efficiency is to be greater than 95%. The particle sizes are to be sub-micron in line with therespirator's intended purpose, for example filtering bacteria, viruses, and aerosol particulates.

Face masks not regulated by the TGA

Face masks intended for use by the general public for non-medical purposes are not medical devices. Masks that are not medical devices are not regulated by the TGA. Examples of such masks include those intended to be used in construction and other industrial applications.

Due to the lack of resistance to fluid penetration, masks designed to certain standards or subclasses of some standards (listed below), may not be suitable for use in medical or surgical settings.

1. Type I, II of EN 14683:2019
2. YYT 0969:2013
3. GB/T 32610-2016
4. T/CTCA 1-2019
5. T/CTCA 7-2019

Masks designed and manufactured to comply only with these standards are not suitable for use as a medical device. These types of masks are not required to be, and should not be, included on the Australian Register of Therapeutic Goods (ARTG).

A suitable standard for reusable masks to demonstrate some of the applicable minimum requirements is ASTM F3502-21. The standard still specifies the masks are not medical devices, but provide further guidelines for manufacturers for this kind of mask.

These masks may still be appropriate for use in non-medical/healthcare settings to assist in reducing airborne disease transmission, along with social distancing measures.

Note that the use of antimicrobial materials, finishes or mechanisms, including that of novel materials, nanomaterials and coatings may be subject to further regulatory scrutiny in consideration of safety and efficacy, as well as potential toxic and adverse effects when these materials or particulates are in contact with skin or is at risk of being inhaled or ingested by the user. Manufacturer should carefully consider the advertising claims used to not incorrectly advertise products as medical devices.

For more information see: Face masks and respirators that are regulated by the TGA.

Post-market Monitoring and Corrective Actions

Manufacturers are required to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

Where a manufacturer becomes aware of a potential performance or safety issue related to their product(s), the issue should be risked assessed as part of their post-market monitoring and corrective actions systems. Ideally, through application of policies and procedures defined in a quality management and the application of risk management in accordance with ISO 14971.

For example, if non-compliance with a relevant performance requirement is identified through application of testing methods, the manufacturer should consider the relevance of that information in the context of the intended purpose of the device, and the potential risk the non-compliance presents to the end users.

Following appropriate investigation and evaluation the manufacturer should determine what further action should be taken to:

- Mitigate any immediate unacceptable risk to users;
  - This could be through notification of issues and associated risks to users, non-supply or varied supply of stock on hand, or recall of product etc.
- Eliminate or minimise the risk associated with the device in the future
  - This could be through appropriate changes the design or production of the device, or variations to the intended purpose etc.

Annex 1- GMDN (Global Medical Device Nomenclature) codes and descriptions

GMDN	Descriptions
35177 Mask, surgical, single use	A disposable device made from fabric or other material placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms while surgery is being performed.
57793 Public Respirator, single use	A form-shaped filtering mask designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from large particles (e.g., blood, body fluids, and airborne particulate materials) and small particles (e.g., bacteria and viruses) when considered necessary (e.g., viral epidemic). It is typically made of multiple layers of non-woven polymers to produce a soft, flexible mask that will create an airtight seal against the user's face and typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire) and/or an exhalation valve. This is a single-use device.
57794 Surgical respirator, single use	A non-sterile filtering mask designed to be placed over the nose and mouth of a healthcare worker to permit normal breathing while protecting the worker and patients from the transfer of microorganisms, blood, body fluids, and airborne particulate materials during medical, surgical, dental, and isolation procedures. It is typically made of multiple layers of non-woven polymers, and incorporates a forming nosepiece (metal wire); it is typically secured using elastic head straps. This is a single-use device.
57792 Antimicrobial surgical respirator	A non-sterile filtering mask designed to be placed over the nose and mouth of a healthcare worker to permit normal breathing while protecting the worker and patients from the transfer of microorganisms, blood, body fluids, and airborne particulate materials during medical, surgical, dental, and isolation procedures; it includes an antimicrobial/antiviral agent to destroy specified pathogens under specified contact conditions. It is typically made of multiple layers of non-woven polymers, and incorporates a forming nosepiece (metal wire); it is typically secured using elastic head straps. This is a single-use device.
64822 Public face mask, reusable	A flexible, loose-fitting mask designed to be placed over the mouth and/or nose of a member of the general public to permit normal breathing while protecting the wearer from the transfer of large particles (e.g., blood, body fluids, and airborne particulate materials) from the environment, it is not a form-shaped filtering device (i.e., not a respirator). It is made of a flexible, porous fabric or paper material and is typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire). This is a reusable device.

GMDN	Descriptions
64821 Public face mask, single use	A flexible, loose-fitting mask designed to be placed over the mouth and/or nose of a member of the general public to permit normal breathing while protecting the wearer from the transfer of large particles (e.g., blood, body fluids, and airborne particulate materials) from the environment, it is not a form-shaped filtering device (i.e., not a respirator). It is made of a flexible, porous fabric or paper material and is typically secured using elastic head straps or ties; it may incorporate a forming nosepiece (metal wire). This is a single-use device.
64963 Half-face respirator body/ filter	A form-shaped respiratory mask with filters intended to be placed over the nose and mouth of a person to permit normal breathing while preventing transfer of large particles (e.g. blood, body fluids, and airborne particulate materials) and small particles (e.g., bacteria and viruses) to and from the wearer (i.e., upon inhalation and exhalation). The mask portion is constructed from pliable synthetic polymer materials designed to create and airtight seal against the user's face, and typically includes ties/ head straps; the filters are typically replaceable. This is a reusable device.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA Laboratories	December 2020
V2.0	Update and insertion of requirements on particulate filtration efficiencies	TGA Laboratories	May 2021
V3.0	Update for readability and information on sampling plans. Clarification of fluid resistance testing expectations for surgical respirators.	TGA Laboratories	August 2021
V3.1	Additional content on details of lab testing from laboratory to match web version.	TGA Laboratories	October 2021

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Therapeutic Goods Administration

Performance Report 2021-22

Contents

Message from the Deputy Secretary

In 2021-22 we continued to take a lead role in adapting to the health environment that has been significantly impacted by COVID-19. Medicines and medical devices associated with COVID-19 were prioritised and their safety and efficacy assessed through stringent pre-market assessments and thorough post-market safety monitoring. Post-market review of COVID-19-related devices including face masks, respirators, and test kits was also a major activity.

During the past year, we continued to undertake our Transformation Program to streamline our business systems and modernise IT infrastructure.

From April to August 2022, the move to our purpose-built facilities in Fairbairn occurred. The new premises includes state-of-the-art laboratories to support our delivery of a world-class regulatory system for therapeutic goods. Demonstrating our commitment to a culture of staff professional development, respect, and inclusion, we continued focusing on maintaining our regulatory science capability as outlined in the *Regulatory Science Strategy 2020–2025*.

Reforms were undertaken to support emerging medical technologies such as Software as a Medical Device, while other enhancements were made to further and safeguard patients through medical device reforms. Simplified pathways and processes for industry will result in faster approval of products while maintaining our high standards of safety and efficacy. We also streamlined the Special Access Scheme and Authorised Prescriber submission processes for medicinal cannabis and made changes to the scheduling of nicotine. Further reforms were achieved by reviewing the Therapeutic Goods Advertising Code 2021.

We continued our leadership role in international collaboration to help build a more globally aligned regulatory framework by establishing legal agreements to facilitate information sharing, working as part of the leadership of the International Coalition of Medicines Regulatory Authorities to enhance cooperation and chairing the International Medical Device Regulators Forum. This work, along with our efforts to ensure safe and effective vaccines and therapeutics through our participation in the Pacific and Southeast Asia, have been driven by the *TGA's International Engagement Strategy 2021-2025*.

Our compliance activities led to the recall of various devices and medicines including face masks, sleep therapy devices and sunscreens, along with the ongoing monitoring of signals of non-compliance with Good Manufacturing Practice.

Finally, we provided important safety monitoring and public awareness, notably in relation to COVID-19 vaccines.

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

Our purpose

The Therapeutic Goods Administration (TGA), as part of the Australian Government Department of Health and Aged Care, is responsible for evaluating, assessing, and monitoring products that are defined as therapeutic goods. We help Australians stay safe by regulating therapeutic goods for safety, efficacy, or performance, and quality.

We regulate the manufacture, import, export, supply and advertising of prescription medicines, vaccines, sunscreens, complementary medicines (including vitamins, minerals, herbal and traditional medicines), medical devices, blood and blood products, cellular therapies, and biologicals.

Consistent with the *Therapeutic Goods Act 1989,* we:

- apply scientific and clinical expertise to assess whether the benefits of a therapeutic good outweigh any risks to health and safety
- assess the suitability of therapeutic goods for supply, import, and export from Australia
- regulate manufacturers of therapeutic goods to ensure they meet acceptable standards of manufacturing quality
- assess the quality and compliance of therapeutic goods on the market, including through laboratory testing where appropriate
- implement a range of regulatory actions that are proportionate to the potential risk arising from non-compliance or emerging safety concerns.

We achieve this by applying risk-based processes for both pre-market assessment and post-market monitoring, as well as promoting regulatory compliance through clear and transparent decision-making, providing education and guidance, and using innovative technologies and ideas to streamline business functions.

Our vision

Our vision is for better health and wellbeing for all Australians through regulatory excellence. This links directly with the Department of Health and Aged Care's vision of better health and wellbeing for all Australians, now and for future generations.

Our strategic framework

By regulating therapeutic goods in accordance with the *Therapeutic Goods Act 1989* and supporting regulations, we contribute to the Department's strategic priorities:

- better health and ageing outcomes for all Australians
- an affordable, quality health and aged care system
- better sport outcomes.

We are committed to delivering our part of the Department's Health Protection, Emergency Response and Regulation program through the protection of the health and safety of the Australian community, and the preparedness to respond to national health emergencies and risks through the regulation of therapeutic goods (including medicines, medical devices, and blood, cell, and tissue products). This applies to goods exported, imported, supplied, and manufactured in Australia.

Measuring our performance

In line with the Australian Government's new expectations for regulator performance and reporting, we have combined our previous KPI Performance Regulator Report and our Performance Statistics Report into this report. We will undertake our regulatory functions by applying 3 principles of regulator best practice:

Continuous improvement and building trust

We:

- use qualitative and quantitative analysis to assess and report on performance, and drive evidence-based continuous improvement
- promote a culture that builds public confidence in our work and trust in our decision-making.

Risk based and data driven

We:

- actively understand, engage with, and effectively mitigate strategic risks to successfully manage our regulatory functions without unnecessarily impeding the operations of regulated entities
- use data sources that meet relevant data assurance standards for assessing and reporting on the quality of statistical information.

Collaboration and engagement

We:

- seek opportunities to inform, engage and consult with our stakeholders and the Australian community
- are receptive to feedback and diverse stakeholder views
- seek to increase transparency in decision-making processes
- provide up-to-date, clear, and accessible guidance and information to assist regulated entities with compliance.

Using these 3 principles as a platform, we have outlined our performance against the strategic objectives outlined in our 2021-2022 Business Plan. Our priorities set out in the 2021-2022 TGA Annual Business Plan are:

- **Product regulation and safety** – including COVID-19 medicines, vaccines and medical devices, and digital transformation
- **Regulatory reform** – through consulting on and implementing initiatives following policy approval from government
- **International engagement** – through activities that promote international information sharing, work sharing, collaboration and regulatory convergence, as well as programs for regulatory strengthening/assistance, and medicines testing in our region
- **Regulatory education and compliance** – through education, monitoring, targeted compliance and enforcement activities and appropriate action.

Priority 1 – Product regulation and safety

1.1. Prioritise COVID-19 medicines and medical devices

1.1.1. We continued to prioritise medicines, vaccines and medical devices that are associated with COVID-19 without compromising safety, and we worked together with our international regulatory counterparts.

The TGA remains at the forefront of the Australian Government's response to the COVID-19 pandemic. In 2021-22 we prioritised the provisional approval of COVID-19 therapeutic goods, including:

- the approval of Moderna's Elasomeran (SPIKEVAX) vaccine for individuals aged 18 years and older in 23 working days
- the approval of Pfizer's Tozinameran (COMINARTY) vaccine for individuals aged 5-11 years and older in 25 working days
- the approval of Pfizer's Tozinameran (COMINARTY) vaccine for individuals aged 12-15 years and older in 32 working days.

To further support our COVID-19 response, we developed new methods of testing for mRNA and viral vector vaccines, carried out lipid testing of mRNA-type vaccines, assessed disinfectant submissions with added COVID-19 claims, and evaluated the sterility and microbiological aspects of COVID-19 vaccines and treatments.

Case Study – Approval of COVID-19 vaccines

During the 2021-22 financial year we granted initial provisional approval for two COVID-19 vaccines, NUVAXOVID (Novavax) and SPIKEVAX (Moderna).

Novavax is the first protein subunit COVID-19 vaccine to receive regulatory approval in Australia. Protein vaccines use a non-infectious component found on the surface of the coronavirus and are manufactured in cells in a laboratory. After vaccination, immune cells recognise the vaccine protein as foreign and launch an immune response against it.

In contrast, the Moderna and Pfizer vaccines are a messenger RNA (mRNA) vaccine. This type of vaccine uses a genetic code called RNA to make the body's cells produce the coronavirus' specific spike protein. The immune system cells then recognise the spike protein as a threat and begin building an immune response against it. The RNA from the vaccine does not change a person's DNA in any way, and the body quickly breaks it down.

The decision to provisionally approve the vaccines was also informed by expert advice from the Advisory Committee on Vaccines (ACV), an independent committee with expertise in scientific, medical, and clinical fields including consumer representation.

1.1.2. We supported small-to-medium enterprises (SMEs), researchers, and those unfamiliar with therapeutic goods regulation to better understand regulatory requirements.

Our dedicated service, SME Assist, has helped SMEs, researchers, start-ups and those unfamiliar with therapeutic goods regulation understand their regulatory and legislative obligations, and we published guidance on our website to provide up-to-date, clear, and accessible information to assist sponsors and manufacturers seeking approval to supply COVID-19 rapid antigen self-tests and point-of-care tests.

1.1.3. We prioritised the development and approval of therapies that assist with the treatment of COVID-19. This includes advisory support to clinical trial researchers and industry, and contributions to international consortia.

In 2021-22, we provisionally approved 7 COVID-19 treatments: GlaxoSmithKline (sotorovimab), Celltrion (regdanvimab), MSD (molnupiravir), Roche (casirivimab + imdevimab), Roche (toxilizumab), Pfizer (nirmatrelvir + ritonavir) and AstraZeneca (tixagevimab and cilgavimab).

Our prioritisation of the provisional approval of these treatments is illustrated by the following examples:

- the approval of Roche Products Pty Ltd's Tocilizumab (ACTMERA) COVID-19 treatment in 40 days
- the approval of AstraZeneca's Tixagevimab and Cilgavimab (EVUSHELD) COVID-19 treatment, for pre-exposure prophylaxis in individuals 12 years and over, in 54 days
- the approval of GlaxoSmithKline's Sotrovimab (XEVUDY) COVID-19 treatment in 65 days.

We continued to give priority to processing of clinical trial notifications related to COVID-19 on request from trial sponsors.

1.1.4. We prioritised the regulatory review of diagnostic tests and medical devices for COVID-19 and provided advisory support to researchers and industry (including SMEs) developing medical devices and tests for COVID-19 patients.

In 2021-22 we prioritised the review of COVID-19 test kits and devices working alongside the Peter Doherty Institute for Infection and Immunity (the Doherty Institute).

Case Study – Post-market review of COVID-19 related test kits and face masks

A post-market review of all COVID-19 test kits, including Polymerase Chain Reaction (PCR) and rapid antigen tests (RATs) against COVID-19 variants of concern, including Delta and Omicron, was commenced. We engaged the Doherty Institute to undertake independent laboratory testing of COVID-19 RATs as part of the review. The review includes a total of 155 Australian Register of Therapeutic Good (ARTG) entries (244 test kits), and, as of 16 November 2022, we have received 76 test reports from the Doherty Institute. Of these, 43 of the reports have been validated by our Laboratories, and certificates of testing have been issued to sponsors and 37 results published on our website. We will continue to publish results as they become available.

Doherty Institute testing validated the sensitivity of RATs as claimed by manufacturers against guidelines set by the World Health Organisation, and testing was performed against the Delta and Omicron variants against the original SARS-CoV-2 strain. Manufacturers provided study data to validate the performance of their test kits, including recombinant protein studies, live virus studies, inactivated virus studies, and clinical studies.

We assessed pre-market applications and carried out post-market reviews of face masks and respirators. All face masks entered in the ARTG, a total of 2,276, underwent a desktop review and laboratory testing to verify their performance. This is the largest single post-market review we have undertaken. Results and findings were released to sponsors, with approximately 80% of ARTG entries cancelled due to sponsor decisions or our findings.

1.1.5. We monitored the safety and efficacy of COVID-19 vaccines through our vaccine safety monitoring system.

Our vaccine safety monitoring system rapidly detects, investigates, and responds to any emerging safety issues. We review and analyse adverse event reports, collaborate with international regulators, and review the medical literature, media, and other potential sources of new safety information as part of our surveillance activities.

During 2021-22 we processed more than 125,000 adverse event reports, including more than 99,000 reports for COVID-19 vaccines, with the majority submitted via the new secure file upload channel.[1] In the same period, we investigated more than 120 potential safety signals for COVID-19 vaccines, resulting in over 55 regulatory actions, including 36 safety-related Product Information updates. Outcomes were communicated to the public and health professionals via weekly updates to the COVID-19 vaccine safety report, and through regular Medicine Safety Updates on our website. As part of the pre-market Risk Management Plan (RMP), in 2021-22 we conducted 317 rounds of evaluation and reviewed 318 updated post-market RMPs, including for COVID-19 treatments and vaccines in short timeframes.

1.2. Regulation of medicines and medical devices

1.2.1. We maintained our high standards of regulation for medicines and medical devices by delivering regulatory decisions within target timeframes.

In 2021-22 we delivered regulatory decisions within target timeframes, where applicable, including:

Prescription medicines

- 345 submissions for new prescription medicines or variations to existing medicines that involve the evaluation of clinical, pre-clinical or bio-equivalence data (Category 1 submissions) were approved in 2021-22, including vaccines and treatments for COVID-19[2]. The mean and median approval times in 2021-22 were 159 and 163 working days respectively, with 100% of applications processed within the legislated timeframe of 255 days[3].

Over-the-Counter-medicines (OTC medicines)

- We received 196 new product applications in 2021-22, which is 17% lower than the 236 applications we received in 2020-21[4].
- We approved 193 new N1-N5 OTC medicine applications (OTC medicine applications are categorised as new medicine (N) or change (C) applications and are further categorised by risk, with N1 low risk, N5 and C4 are highest risk) in 2021-22, which is 2% lower than the 197 we approved in 2020-21[5].

[1] Please refer to Table 38, Appendix 7.1.
[2] Please refer to Table 1, Appendix 1.1.
[3] Please refer to Table 3, Appendix 1.2.
[4] Please refer to Table 12, Appendix 2.2.1.
[5] Please refer to Table 9, Appendix 2 for a glossary of application categories, and to Table 13, Appendix 2.2.2 for the statistics.

- 803 applications to vary existing medicines were received in 2021-22, which is 10% more than the 731 applications we received in 2020-21[6].
- 598 applications to vary existing medicines were approved in 2021-22, which is 5% higher than the 572 applications we approved in 2020-21[7].
- The percentage of applications processed within target timeframe was 100% for N2 new product applications, and 87% and 95% respectively for C2 and C3 variation applications[8].

Registered complementary medicines

- We approved 5 new registered complementary medicine applications in 2021-22, compared to 9 applications approved during 2020-21[9]. All applications were completed within legislated timeframes.

Assessed listed medicines

- No new assessed listed medicine applications were approved in the 2021-22 period, compared to 2 approved in 2020-21.

Listed medicines

- 14 new ingredients for use in listed medicines were approved in the reporting period, an increase from 5 new ingredients that were approved in 2020-21[10].
- We completed processing 6 consent to supply applications under section 14/14A of the *Therapeutic Goods Act 1989* during 2021-22, compared to 36 applications in 2020-21. We also extended 582 existing consent applications.[11]
- We processed 178 applications to vary existing medicines under subsection 9D(1) of the Act in 2021-22, compared to 142 applications in 2020-21[12].
- In addition to the above approvals, 1,929 new listed medicines were entered in the Australian Register of Therapeutic Goods (ARTG) in this period, compared to 2,184 listed medicines in 2020-21[13].

Unapproved medicines

- We approved 125,736 Special Access Scheme Category B (SAS B) applications and 12,172 Authorised Prescriber (AP) applications during 2021-22[14]. Approvals increased by 15.7% and 125% respectively compared to 2020-21, when we approved 108,674 SAS B applications and 5,398 AP applications. The significant increases are primarily due to the sustained growth in SAS and AP applications for medicinal cannabis products.

[6] Please refer to Table 12, Appendix 2.2.1.
[7] Please refer to Table 11, Appendix 2.1.
[8] Please refer to Table 11, Appendix 2.1.
[9] Please refer to Table 16, Appendix 3.
[10] Please refer to Table 20, Appendix 5.1.
[11] Please refer to Table 24, Appendix 5.5.
[12] Please refer to Table 23, Appendix 5.4.
[13] Please refer to Table 22, Appendix 5.3.
[14] Please refer to Table 56, Table 57 and Table 58, Appendix 11.1 for SAS B approvals, and to Table 63, Appendix 11.3 for AP approvals.

- 239 SAS B applications for biological products in 2021-22 were approved, which is a 40% decrease compared to 399 applications approved during 2020-21[15].

Medical devices

- We processed 7,624 medical device (including In Vitro Diagnostic devices), disinfectant and variation applications in 2021-22, and 6,120 applications were approved.
- We granted 278 conformity assessment certificates to manufacturers of medical devices in 2021-22,[16] certifying that those devices meet fundamental safety and performance standards.
- The mean and median processing timeframes for conformity assessment applications were 139 and 168 business days respectively[17]. 100% of applications were processed within the legislated timeframe of 255 days.

Laboratory testing

- Laboratory staff continued to be directly involved in providing advice and developing strategies around various COVID-19-related issues, specifically vaccines, hand sanitisers, ventilators, disinfectants, and Personal Protective Equipment (PPE), as well as assisting other areas of the Australian Government.
- We tested 1,738 medical devices in 2021-22, which is a 210% increase from the 827 devices tested in 2020-21. This was predominantly due to the testing of face masks, respirators, and COVID-19 Rapid Antigen Tests (RATs) included in the ARTG, and testing conducted to support Commonwealth, state, and territory procurement activities[18].
- Review statistics regarding face masks are as follows:
    - As of 30 June 2022, there are 2,276 ARTG entries included in the face mask review, of which:
        - 1,364 face mask entries were cancelled by the sponsor
        - 445 face mask entries were cancelled by a delegate of the Secretary.

Inspections

- Much of our work program continued to be shaped by COVID-19, with a focus on inspections and assessments for vaccines and treatments for Australia and the Indo-Pacific region.
- We undertook 104 overseas remote Good Manufacturing Practice (GMP) inspections[19] and 139 domestic GMP inspections[20] (which were performed remotely or a combination of remote and onsite components) in 2021-22, compared to 54 overseas inspections and 210 domestic inspections undertaken in 2020-21. GMP describes a set of principles and procedures that when followed helps ensure that therapeutic goods are of high quality.
- We recommenced onsite overseas inspections in June 2022 using a risk-based approach and conducted one vaccine-related inspection.

[15] Please refer to Table 58, Appendix 11.1.
[16] Please refer to Table 39, Appendix 8.1.1.
[17] Please refer to Table 41, Appendix 8.1.3.
[18] Please refer to Table 76, Appendix 14.
[19] Please refer to Table 68, Appendix 12.2.
[20] Please refer to Table 66, Appendix 12.1.

Licensing and clearance

- During 2021-22 we expedited the processing of licensing and clearance applications, processing 571 GMP applications, issuing 14 new licenses, varying 129 GMP licenses and issuing 178 GMP certificates, compared to 928 GMP applications processed, 13 new licenses issued, 233 GMP licenses varied, and 154 GMP certificates issued in 2020-21.
- We assessed 8,902 GMP clearances and approved 8,103 in 2021-22, in comparison to assessing 7,302 clearances and approving 6,778 in 2020-21[21]. GMP Clearance is required to determine whether overseas manufacturing sites comply with the principles of GMP for products being supplied to Australia.

Recalls

- In 2021-22 we coordinated 819 recall actions compared to 880 actions in 2020-21[22]. Recall actions involved global corrective actions for millions of sleep therapy devices, multiple medical device recall actions following the revelation of falsified sterility data, and the recall of a popular brand of sunscreen due to the presence of benzene.

1.2.2. We have responded to scientific advancements and emerging technologies to support timely access to new therapeutics.

Advances in technology and software production have led to a large increase in Software as a Medical Device (SaMD) products on the market, requiring greater clarification of the regulatory requirements to ensure patient safety. SaMD encompasses various applications, such as mobile applications to analyse rapid antigen tests to detect COVID-19 and systems that diagnose tumours from radiology images, many of which use Artificial Intelligence.

Case Study – Software as a Medical Device (SaMD) reform project

In 2021-22 the government refined and clarified the regulation of software based medical devices, including software that functions as a medical device in its own right (SaMD). SaMD refers to various technologies including mobile applications, web applications, server-based systems, traditional desktop packages, cloud-based systems, or any combination of these. Since February 2021, we have engaged industry extensively to develop detailed guidance to assist many new developers who are now sponsors, as well as providing educational webinars, some of which were delivered by ANDHealth for the sector regarding:

- the boundaries of regulation for software and excluding some products that are low risk or where there are alternative oversight mechanisms. To avoid unnecessary regulatory oversight, certain clinical decision support software was excluded, where there is no significant risk to safety, and they met certain criteria
- new classification rules for programmed and programmable medical devices and software that diagnose, monitor, or treat diseases and conditions
- amendments to existing requirements in the Essential Principles from the *Therapeutic Goods Act 1989* in relation to cyber security, management of data and information, and requirements relating to development, production, and maintenance to provide greater clarity.

[21] Please refer to Table 69, Appendix 12.3.
[22] Please refer to Tables 72-75, Appendix 13.

1.2.3. We continued to improve the transparency of our activities.

During the COVID-19 pandemic we experienced unprecedented public interest regarding the safety of medicines and vaccines, with large numbers of people searching our website for information about adverse events. We received an increase in reports of suspected adverse events, from 59,639 notifications received in 2020-21, to 125,873 received in 2021-22[23]. The increase in the number of adverse event reports and traffic on our website resulted in database performance issues, including time-outs and the inability to download search results.

To maintain transparency of medicine and vaccine adverse events, we created a trial (beta) version of the Database of Adverse Event Notifications (DAEN) for medicines. The beta version includes interactive tables and graphs, a mobile-friendly interface, and additional data download functions, improving how this information is displayed on our website.

There were 39 consultations opened in 2021-22 via the TGA Consultation Hub. These consultations covered many topics of regulation, including adoption of international scientific guidelines in Australia, amendments to the application process for inclusion of Class 1 medical devices, repurposing medicines, and improving patient access to critical medicines in acute-care settings. Our consultation process is a critical mechanism of informing regulatory reforms and policy changes for consideration by government.

Case Study – Repurposing of medicines second public consultation

The repurposing medicines consultation received 27 responses from patients and patient groups, health professionals, academia, and the pharmaceutical industry. We received important advice including:

- clarification regarding data sharing and ownership, regulatory, manufacturing, and operational responsibilities, as well as cost sharing that will be required when repurposing off-patent medicines
- making the patient voice a priority
- rare diseases and unmet needs should be focus areas
- real-world data insights should be considered early in the process of prioritisation
- a streamlined process with simpler data requirements would reduce the burden on sponsors when applying for the repurposed indication.

Feedback from this consultation is now shaping regulatory reforms for consideration by government.

[23] Please refer to Table 38, Appendix 7.1.

1.3. Capability development

1.3.1. The Regulatory Science Strategy 2020-2025 aims to make sure that we continue to make the best possible regulatory decisions, by ensuring that our regulatory scientists are capable, collaborative, communicative, and responsive to future challenges and emerging technologies.

The first key focus area of the Regulatory Science Strategy is to 'maintain and build skills in regulatory science'. To provide training and development opportunities that allow our staff to maintain their scientific expertise and further develop their skills to meet future challenges, we:

- developed formal induction e-learning modules
- rolled out the Regulatory Scientist Capability Framework across our Medicines Regulation Division to support consistency in job descriptions
- developed a Continued Development Framework to empower staff and managers to maintain their technical and regulatory skills.

We also shifted resources to ensure that our regulatory scientists are capable, collaborative, communicative, and responsive to future challenges and emerging technologies, in line with the Strategy.

1.4. Digital transformation

1.4.1. The four-year digital transformation program will deliver simpler, faster, and more secure interactions between industry and government to apply for, track, pay, and manage regulated and subsidised health-related products and services.

Our Transformation Program made progress across several initiatives this year, to reduce the regulatory burden on industry and improve access to information for health providers and consumers. We conducted consultations with internal and industry stakeholders over the past year to define current prescription medicine processes, identify common difficulties and 'pain points' that stakeholders experience, and suggest potential solutions to those issues. The recommendations from the user research were:

- user journeys across the website and transaction portal
- recognise different usage patterns, for example where infrequent use equals "first time, every time"
- provide support channels to improve the quality of applications, self-service, and reduce burden on our resources
- use service channels most relevant for the audience, such as website, portal, Electronic Data Interchange (EDI), and other external channels
- consolidate existing portals into a single point of contact
- present information and services tailored to the audience
- use analytics to inform decisions, such as prioritising which services to uplift to the new portal.

This feedback has been incorporated into the Transformation Program planning to build new TGA services in the Health Products Portal.

The proposed single point of entry will allow quick and easy access for stakeholders to apply for products to be included on the ARTG. The new portal aims to streamline the application process, support users to manage their applications and make payments, while increasing the transparency of the progress of an application in the assessment process.

1.4.2. We continued to modernise our services (eBusiness Services/TGA Business Services), and the redevelopment of the ARTG, as well as making enhancements to support reporting and sharing of adverse event data for medicines and vaccines.

The program to modernise our service experience began with user research to better understand the preferred experience of our customers. Milestones included the release of an updated public portal for advertising compliance and improvements to ARTG searching. The updated features of the portal include:

- new forms to facilitate reporting of non-compliance and advertising enquiries
- applications to use restricted representations in advertising
- a newly launched trial ARTG public search tool to make information easier to find.

We have also progressed improvements to how we share and receive medicine and vaccine adverse event reports. Based on feedback from public consultation, we created the ability for sponsors to access adverse event reports relevant to their medicines using their existing log-in details. This will replace the need for sponsors to email us to request reports, delivering better and faster access to relevant adverse event data with less effort.

We have investigated how we can make it easier for health professionals to report adverse events to us by investigating options for embedding reporting in General Practitioner practice management software. We sought opportunities for collaboration and engagement by liaising with health professionals regarding their requirements, and by consulting software vendors to ascertain the possibilities for the software.

1.4.3. We redeveloped our website and repositioned it onto the GovCMS platform, while ensuring a consistent user experience across all our digital channels.

As part of the digital transformation, in order to launch our new website, more than 110 web content types and topics were assessed, more than 4,000 old web content pages were archived, and approximately 1,250 people were consulted. This has allowed us to deliver improvements to:

- the website interface and functionality, to make it easier to find and understand the information required by users
- navigation and search enhancements to provide quicker search results
- move old website content to be archived on the National Library of Australia web archive, TROVE.

Following these actions, the new website was launched on 30 August 2022, with a modern and simple interface and improved search function. While the new website addresses many straightforward enquiries, more complex enquiries will still come through to our enquiry channels.

Some stakeholders have told us they have experienced challenges getting the information they need when contacting us or have experienced delays in receiving a response. To help address these concerns, we are undertaking an enquiry management project that will modernise our

enquiry channels. In 2021-22, we completed the 'discovery' phase of the project and gained a better understanding of how enquiries are handled and the gaps in our existing processes.

1.4.4. We continued to implement a new system for medical device post-market reviews and improving timeliness and the detection of potential safety problems.

We have managed an increased number of systematic medical device post-market reviews. An enhanced IT system was implemented to support more efficient submission of evidence and tracking of reviews.

In addition, we undertook further preparation for the introduction of a Unique Device Identifier (UDI) System, with a plan for voluntary use of UDI in 2023. The UDI system will allow tracking and tracing of medical devices including those that have been implanted in patients if the UDI is used throughout healthcare and supply chains. This will allow doctors to notify patients quickly if there is a medical device safety issue.

1.5. New state of the art laboratories

After 30 years in Symonston, we relocated to new premises in Fairbairn, also in the ACT, in 2022. The location comprises 2 purpose-built buildings – an office building and a dedicated laboratory building. Most of our staff relocated between April and June, with the Laboratories Branch relocated in August. The laboratories have been constructed specifically to meet our requirements. The transition was undertaken as planned to minimise the impact on the output of the laboratories and the timeliness of regulatory decisions and safety monitoring actions upon moving. The custom-built laboratories will help maintain our reputation as a world-class regulator by enabling continuous improvement and building trust, risk-based and data-driven regulatory practices and promoting collaboration and engagement.

Priority 2 – Regulatory reform

2.1. Prescription medicines

2.1.1. We implemented a risk-based program of Good Clinical Practice inspections of Australian clinical trials of medicines and biological products

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. Compliance with GCP provides assurance that the rights, safety, and well-being of clinical trial participants are protected and that the trial data generated are credible.

Clinical trials of medicines and biologicals are regulated under the Clinical Trial Notification (CTN), or Clinical Trial Approval (CTA) schemes, both of which are subject to our GCP Inspection Program. We have published guidance on the GCP Inspection program on our website to provide sponsors with further information about the program's scope and process. This guidance describes how we prioritise and schedule GCP inspections, the kinds of inspections we might conduct, the inspection process, and how we report and follow-up on inspection.

We also held a series of webinars introducing the GCP inspection program in May-June 2022, following publication of guidance on the program. The webinars reached over 1,200 participants who were interested in learning about how we verify that clinical trial sites are compliant with Australian and internationally accepted standards.

2.1.2. We updated the Pharmaceutical Inspection Cooperation Scheme (PIC/S) guidance to reflect current best practice for requirements for medicines manufacturing quality.

We use internationally harmonised manufacturing standards, such as the PIC/S Guide to GMP, to allow manufacturers to operate in an international environment. Throughout 2021-22, we have been very active in improving the global framework for regulating manufacturing standards for medicines, by leading or participating in working groups of the PIC/S. These include the PIC/S working groups on inspection reliance, remote assessments, and Annex 1, as well as the Expert Circle on Quality Risk Management and cross contamination in shared facilities.

Following a consultation process in 2021-22 with stakeholders in the TGA Industry Working Group on GMP, we adopted the PIC/S guide to GMP version 15 on 1 July 2022. The adoption process involved assessment of the key changes with the new Annex 2A for the manufacture of advanced therapy medicinal products for human use and minor edits to Annex 2B for the manufacture of biological medicinal substances and products for human use which was previously Annex 2.

2.2. Complementary medicines and sunscreens

2.2.1. We developed mandatory requirements for ingredient applications for listed medicines to provide transparency to applicants on the information we require, and to enable more efficient screening and evaluation of these applications.

During 2021-22 we continued to review and address industry feedback to finalise mandatory requirements and associated guidelines when applying for a new substance for use in listed medicines. In response to industry feedback, we also developed new compositional guideline

templates and refined draft guidelines for microorganism characterisation for listed and registered complementary medicines.

Following industry and public consultation, including 2 industry webinars, we published revised Evidence Guidelines for Listed Medicines. The revised Guidelines provide greater clarity regarding:

- the purpose of the Guidelines
- the legislative basis for requiring efficacy for listed medicines
- evidence sources for traditional medicines
- efficacy expectations
- evidence requirements for supplement indications
- further explanation on what we consider is a critical appraisal.

2.2.2. We considered approval pathways for sunscreen active and excipient ingredients to provide transparency to applicants on the information required by us, and to enable more efficient screening and evaluation of these applications.

The safety and quality data requirements for new sunscreen active and excipient ingredients were reviewed, and after considering industry feedback, these requirements were appropriately adjusted to address their topical dosage form. We also drafted amendments which allows for expanded use of Comparable Overseas Bodies evaluation reports, thereby supporting abbreviated evaluations of applications for new sunscreen active and excipient ingredients.

2.2.3. Further enhancement of the listed medicines post-market compliance scheme as part of our digital transformation project.

During 2021-22, a greater number of targeted compliance reviews were conducted based on signals intelligence received through various avenues such as complaints, pro-active scanning of the ARTG, referrals from other agencies, actions from international counterparts, adverse events and our laboratory testing results.

We conducted weekly ARTG scanning of newly listed medicines to detect potential non-compliance of a medicine prior to the sponsor marketing the medicine. Early engagement with the sponsor soon after their listing also allows sponsors to update their product before they suffer commercial losses. Signals of potential non-compliance were triaged and assessed for alleged breaches and actions taken were dependent on the risks posed. Actions from signals ranged from educational correspondence, warning letters and compliance reviews to infringement notices. 2,115 newly listed medicines were monitored via ARTG scanning, with 221 risk-assessed for potential compliance issues. 19 were deemed to be signals of potential non-compliance and were further investigated.[24]

During the reporting period we introduced new internal work management pathways to better capture complaint and referral actions, which enabled us to effectively track low-level compliance actions and outcomes and build sponsor compliance profiles.

Targeted reviews in 2021-22 included medicines containing safrole, caffeine and vitamin A, medicines that required warnings for use during pregnancy and sunscreen products. Indications

[24] Please see Table 28, Appendix 5.8.

targeted included COVID-19, arthritis, and serious gastrointestinal conditions. In addition, a sponsor with a long history of non-compliance was targeted.

We publish results of all listed medicine compliance reviews in a database on our website which allows consumers to make more informed choices about the efficacy and safety of their medicines. The searchable database includes information about whether a medicine can continue to be used safely as directed, the recommended actions for consumers to take in relation to the medicine, and our findings relating to the safety and efficacy of the medicine. We published 78 compliance reviews in 2021-22.

2.2.4. With changes to the regulation of sports supplements, we undertook a comprehensive compliance program.

We undertook compliance actions under the Sports Supplements Compliance Plan including an intelligence review to identify non-compliance cases, laboratory testing of over 20 products, finalising existing investigations, launching a civil action, and running cases/investigations with the regulatory response to be determined, proportionate to the behaviour and investigation outcomes.

2.3. Medical devices

2.3.1. We completed the implementation of business processes to enable Australian Conformity Assessment Bodies (CAB) to provide conformity assessment for medical devices.

Since 1 July 2021 we accept conformity assessment documents issued by an Australian CAB including those issued for medical devices that contain medicines or materials of animal, microbial, recombinant, or human origin; and Class 4 in vitro diagnostic (IVD) medical devices. We published external guidance and the application form in July 2021 to allow applicants to apply to become an Australian CAB.

2.3.2. We implemented the reclassification of devices to align with the European Union Medical Device Reforms where appropriate.

Following extensive reviews and public consultation, we implemented the reclassification of certain medical devices to align with changes being adopted under the European Union (EU) Medical Device Regulations (where appropriate).

Actions include:

- regulatory changes to the definition and scope of medical devices
- development of medical device patient information materials
- refinements to the definition for systems or procedure packs
- community expectations for regulatory oversight of medical device clinical trials
- reclassification of surgical mesh.

Reclassification of 6 categories of medical devices to align with the EU's Medical Device Regulations came into effect on 25 November 2021.

Given the significant changes in the EU framework, other changes in Australia have meant decreased regulatory burden as some processes have been further streamlined to a risk-based approach to reviewing applications rather than a mandatory approach.

2.3.3. We undertook further preparation for the introduction of a Unique Device Identifier (UDI) system.

We undertook further preparation for the introduction of a UDI System, with release of a "sandpit" version of the UDI database in mid-2022 for stakeholder feedback and for voluntary use by sponsors and manufacturers to submit data in 2023. Several pilot sites being negotiated with hospitals will also be critical to the implementation of the UDI. The UDI will improve patient safety and post market surveillance when fully adopted in supply chain, clinical and other health systems, by enabling easier and faster identification of patients who have been implanted with a device of concern (a device with a safety incident or recall related to that device), and easier identification and removal of those devices from stocks, storage, and distribution, helping prevent any further devices of that model being implanted or used. The UDI will also allow patients, consumers, and health professionals to easily access information about the devices that they use, including if there is a device safety incident or recall related to that device.

In progressing the UDI implementation, we sought industry feedback through a range of forums and consultations and delivered a series of webinars on the Australian UDI system. The engagement has provided feedback on the considerations for the Australian UDI, including global alignment, Global Medical Device Nomenclature (GMDN), challenges for the implementation of UDI by healthcare providers, and data elements. Among other benefits, the implementation of UDI will allow more accurate identification of medical device models in reports and complaints received by us.

2.3.4. We have continued to improve post-market monitoring systems for medical devices, including implementing methods for early detection and action on emerging safety issues, thereby allowing us to notify consumers earlier.

We participate in regular meetings with international medical device regulators to exchange signals and concerns in relation to medical device safety and quality signals. This allows us to identify and evaluate issues experienced internationally and instigate action even if the signal has not emerged locally. In addition, we are exploring data analytics capability to identify emerging trends and signals from the reporting of adverse events.

Further, we have reviewed the current rules that exempt manufacturers from reporting adverse events in some circumstances and will consult with stakeholders on any proposed changes. Proposed changes will improve the reporting of adverse events and enable earlier detection of signals. Additionally, in November 2021 we commenced the development of a new medical device sponsor vigilance program which will help us verify and educate sponsors compliance with legislative requirements. A pilot program is scheduled to commence in 2023.

2.3.5. We have continued to implement the Action Plan for Medical Devices.

Following on from the publication in 2019 of the Action Plan for Medical Devices, we have undertaken numerous activities in order to improve the process for devices gaining access to the market. These include:

- webinars and stakeholder workshops regarding the approaches to handling the transitioning and assessment of medical devices approved under the EU Medical Devices Directive (MDD)
- new applications under the new EU Medical Devices Regulations (MDR)
- the re-classification of certain medical devices.

These devices include:

- active medical devices for therapy with diagnostic function
- spinal implantable medical devices (motion preserving)
- devices used in direct contact with the heart, central circulatory system, or central nervous system
- medical devices that administer medicines or biologicals by inhalation
- active implantable medical devices
- medical devices that are substances introduced into the body via body orifice or applied to the skin.

We have published:

- guidance for industry relating to regulatory amendments for first aid kits and system or procedure packs
- guidance on regulations of software and applications which meet the legislative definition of a medical device in Australia
- guidance and sponsor notification forms for the 5 reclassified medical devices
- updated guidance for the personalised medical devices sector
- guidance regarding requirements for Patient Information Leaflets (PILS) and Patient Information Cards (PICs).

Five working groups with consumer representation have been established and have been meeting regularly during the reporting period, including the Breast Implant Expert Working Group, the Medical Device Consumer Working Group, the Women's Health Products Working Group, the Ventilator Expert Working Group, and the Surgical Mesh Expert Working Group.

Fact sheets have been published to provide information and assist consumers, healthcare professionals, and industry, including the digital mental health fact sheet, breast implant associated-anaplastic large cell lymphoma (BIA-ALCL), purchasing approved RAT kits/self-tests and COVID-19 self-testing on correct use of these tests.

On 29 October 2021, amendments to the Therapeutic Goods (Medical Device) Regulations 2002 came into effect, allowing greater flexibility in how patient information materials can be supplied with implantable and active implantable medical devices in Australia.

2.3.6. Conducting public consultations, we provided advice to government on the:

- requirements for medical devices used in clinical trials
- potential inspections of the systems used by sponsors for reporting and tracking adverse events
- enhancements to adverse event reporting, including whether adverse event reporting by healthcare facilities should be mandated.

We regularly meet with state and territory health departments to discuss matters including COVID-19 RATs, Personal Protective Equipment, and other regulatory actions relating to medical devices. A suite of measures has commenced to enhance the post-market adverse event reporting and surveillance of medical devices.

In late 2022 we undertook a public consultation on proposed regulatory changes to strengthen safety oversight of clinical trials for medical devices.

Further examples of other measures taken include working with the Australian Commission on Safety and Quality in Health Care (ACSQHC) to explore ways to implement the mandatory reporting of adverse events by healthcare facilities, improving the ways to report adverse events (including possible use of smartphone applications), reviewing adverse event reporting exemption rules, a medical device vigilance program, a pilot program to enable auditing and inspection of medical device sponsors (Unique Identifier System) and ongoing monitoring to support the re-classification of surgical mesh.

In December 2021 we published a discussion paper on Mandatory Reporting of Medical Device Adverse Events by Healthcare Facilities for public feedback. We are now preparing options to implement the scheme, in partnership with states and territories and the ACSQHC.

2.4. Medicines and Chemicals Scheduling

2.4.1. We ensured that the implementation of changes to the scheduling of nicotine for use in e-cigarettes are adequately supported by related regulatory change, stakeholder interaction and communication once changes came into effect in October 2021.

On 1 October 2021, the scheduling was amended to make all Nicotine Vaping Products (NVPs) prescription-only medicines. This had the effect of preventing, under the Therapeutic Goods Act 1989, individuals from legally buying NVPs (such as nicotine e-cigarettes, nicotine pods and liquid nicotine) from overseas websites without first getting a prescription. This aligned Commonwealth legislation with existing state and territory laws that prevented the domestic supply of NVPs to consumers without a prescription.

To adequately support the changes, we:

- delivered an educational campaign to inform stakeholders about the changes to how NVPs can be accessed, prescribed, and supplied in Australia
- following public consultation, we made a product standard to set minimum safety and quality requirements for NVPs (Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021)
- progressed amendments to the Therapeutic Goods Regulations 1990 to facilitate pharmacies stocking unapproved NVPs in their dispensaries in anticipation of prescriptions and our required approvals
- granted a legal permission which allows pharmacies and pharmacy marketing groups to advertise (subject to certain strict conditions) where an individual may obtain NVPs with a prescription (to facilitate consumers accessing NVPs through lawful channels). We analysed vaping and e-cigarette import data over a 12-month period and established risk ratings for known importers and suppliers - the intelligence assessment formed part of the broader compliance response to the October 2021 nicotine scheduling changes, which included targeted education initiatives and monitoring activities for border compliance.

2.4.2. We worked with stakeholders to develop a new application form for proposing scheduling changes and a database to make the Poisons Standard publicly searchable.

We met with representatives from each state and territory, to introduce an exposure draft of the Poisons Standard. We worked with the Office of Parliamentary Counsel to modernise the Poisons Standard to meet current legislative drafting standards, ahead of implementation of the Standard in early 2023. As a result, the modernised Standard will be easier to navigate and understand and will support the development of a searchable Poisons Standard database. After input from stakeholders, the online application form will be operational in 2022-23.

2.4.3. Together with major stakeholders, we considered improvements to 'Appendix M' of the Standard to facilitate down-scheduling of appropriate prescription-only substances to pharmacist-only.

Appendix M of the Poisons Standard is intended to include substances that have formerly been scheduled as Schedule 4 (S4) and thus have required a prescription by a medical practitioner, but if rescheduled to Schedule 3 (S3) could be dispensed by a pharmacist with specific controls in place that help appropriate use.

There has been no progress during 2021-22, but improvements targeted to improve Appendix M in the Poisons Standard will continue to be considered into 2023.

2.5. Medicinal Cannabis

2.5.1. We progressed reforms and improved business processes to the regulation of medicinal cannabis products in Australia, including requirements relating to supply, manufacture, labelling and packaging.

We implemented reforms to the patient access framework in November 2021, streamlining the Special Access Scheme (SAS) and Authorised Prescriber (AP) submission process by accepting 'unapproved' medicinal cannabis applications under active ingredients rather than brand name. The reforms aimed to reduce prescriber administrative burden and further improve patient access by enabling continuation of therapy in the event of a product shortage or discontinuation, or when a decision is made to switch to another equivalent product for reasons such as cost.

Access to certain medicinal cannabis products was streamlined through inclusion in the AP 'Established History of Use' pathway by reference to active ingredient categories, dosage forms and indications. When using this pathway, prescribers do not require Human Research Ethics Committee approval or specialist college endorsement by applying to us to become an AP.

In addition, significant enhancements were progressed to the SAS/AP Online System to support the uptake of the AP pathway, including improvement to the usability of the system and improvements to the mandatory six-monthly reporting functionality to better meet prescriber reporting needs.

The Therapeutic Goods (Standard for Medicinal Cannabis) (TGO 93) Order 2017 is a standard that specifies minimum quality requirements for unapproved medicinal cannabis products imported into and supplied or manufactured in Australia, and the Order was amended in March 2022, with most of the changes applying to medicinal cannabis products released for supply on or after 1 July 2023.

The government endorsed regulatory reforms to medicinal cannabis manufacturing, labelling, and packaging requirements, requiring overseas manufacturing of medicinal cannabis to hold

evidence of Good Manufacturing Practice (GMP) compliance. Australian manufacturers must operate in compliance with the Australian Code of GMP for medicines and be licensed by us.

In addition, labels are required to clearly differentiate between medicinal cannabis products that are based on plant material, broad spectrum extracts, full spectrum extracts and isolates (of the active ingredient). Different information is required in each case - more information is required for active ingredients that are not present as isolates. Labelling requirements aim to help prescribers and consumers identify the goods and know how to use and store them safely. Products must also have child-resistant packaging when there is a high risk associated with accidental ingestion. These reforms provide greater protection to patients by broadly aligning GMP for imported products with those that already apply to domestically manufactured goods.

Priority 3 – International engagement

The TGA's International Engagement Strategy 2021-2025 describes how working with our international regulatory counterparts will benefit Australians through a more globally aligned regulatory framework. Reduced regulatory burden on industry, a fit for purpose regulatory system that is responsive to the latest medical and scientific developments and enhanced global identification of safety signals leads to improved access to health products and better safeguards for the Australian community.

The strategy consists of 4 goals:

- Goal 1: Build a globally aligned regulatory framework that fosters sovereign decision making.
- Goal 2: Pre-market global collaboration and information sharing with comparable overseas regulators to reduce regulatory burden.
- Goal 3: Post-market global surveillance utilising international networks to monitor product safety and quality and maintain supply chains.
- Goal 4: Strengthen regional regulatory capabilities for safer and effective therapeutics.

3.1. Activities during 2021-22

3.1.1. Goal 1. Build a globally aligned regulatory framework that fosters sovereign decision making.

Legal agreements to facilitate information sharing

Establishment of legal agreements with our international regulatory counterparts ensures Australia's access to quality, safe and effective therapeutic goods is maintained when sharing confidential information. We currently have 30 agreements for confidential information sharing in place with regulatory authorities in 25 countries and are a party to 5 treaty-level country mutual recognition agreements. Two new agreements were established in this reporting period:

- TGA – Swedish Medicines Products Agency Agreement for confidential information sharing on regulation of medical devices (signed 9 June 2022)
- TGA – Brunei Darussalam Medicines Control Authority Memorandum of Understanding for sharing of confidential information (signed 26 September 2022).

Case Study – TGA-Brunei Darussalam Medicines Control Authority MoU

The TGA signed a Memorandum of Understanding (MoU) with the Brunei Darussalam Medicines Control Authority (BDMCA) at a virtual signing event on 26 September 2022, following TGA approval of the MoU on 9 June. The MoU was jointly signed by the Chairman of the BDMCA and the Deputy Secretary, Health Products Regulation Group, and witnessed by the Permanent Secretary, Brunei Ministry of Health. The Australian High Commissioner to Brunei was present at the signing.

Brunei officials noted the MoU's support for information exchange on the regulation of therapeutic products, and the enhanced opportunities for the exchange of information on the regulatory framework of pre- and post-market products. The MoU is a great example of work under our international engagement strategy and will contribute to capacity building for BDMCA health professionals.

The development of the MoU was strongly supported by the Department of Foreign Affairs and Trade (DFAT) and the Australian High Commission in Brunei, with the emergence of the COVID-19 pandemic. Australia also supported Brunei with 100,000 doses of Australian-made VAXZEVRIA under an Emergency Use Authorisation. Additionally, DFAT worked closely with Brunei during its ASEAN (Association of Southeast Asian Nations) Chairmanship year in 2021 to address the impacts of COVID-19 on mental health, and co-sponsored Brunei's East ASEAN Summits Leaders' Statement on Mental Health Cooperation and Workshops in November 2021.

Interactions with our international regulatory counterparts

From 3-5 November 2021, we hosted a series of interactive presentations on Good Manufacturing Practices for vaccines and biological medicines for the Thai Food and Drug Administration. The training material was delivered in Thai and the sessions were productive and collaborative.

As part of the Free Trade Agreement negotiations between Australia and India, on 1 March 2022 we hosted a delegation of Indian Government commerce, trade, regulator, and pharmaceutical industry officials to discuss opportunities for closer regulatory collaboration with the TGA.

In May 2022, we met with the South African Health Products Regulatory Authority (SAHPRA) to provide advice in developing its regulatory capabilities and procedures. We have since set up a future meeting to continue to provide our support in these areas.

We also participated in the World Health Organisation global benchmarking tool assessment of the Republic of Korea's regulator in May 2022.

International Medical Device Regulators

The International Medical Device Regulators Forum's Working Group on Personalised Medical Devices (PMDs), chaired by the TGA, developed guidance documents for providing harmonized recommendations for the regulation of PMDs, including for regulation of their point-of-care manufacture.

3.1.2. Goal 2. Pre-market global collaboration and information sharing with comparable overseas regulators to reduce regulatory burden.

International Coalition of Medicines Regulatory Authorities

The International Coalition of Medicines Regulatory Authorities (ICMRA) was established to better safeguard global public health by facilitating greater cooperation. It enables Heads of Medicines Regulatory Authorities to exercise concerted strategic leadership during a global public health crisis and shared regulatory issues and challenges.

Since the start of the COVID-19 pandemic, international collaboration between regulators has been critical to Australia's response. As Vice Chair of ICMRA, we played a leading role. Interactions through email have occurred daily, and by videoconference weekly, for much of the pandemic, and we have shared information in 'real time' as well as collaborating formally on product reviews and important safety concerns. As a relatively small regulator, Australia has received far more information than we have contributed, though we have played a global leadership role in chairing/co-chairing the main global initiatives, building robust processes for international collaboration, and leading initiatives on vaccine safety and vaccine communication as chair of the Vaccine Pharmacovigilance Network (VPN).

International work-sharing for prescription medicines and medical devices

Access Consortium

The Access Consortium is a medium-sized coalition of like-minded regulatory authorities (Australia-Canada-Singapore-Switzerland-United Kingdom) that work together to promote greater regulatory collaboration and alignment of regulatory requirements. One significant area of collaboration is work-sharing the evaluation of a wide range of new chemical entities and generic medicines which streamline the evaluation process and reduce duplication of evaluation effort.

The Access Consortium has several active working groups in place and participates in work-sharing initiatives for the following:

- In 2021 we chaired the Access Consortium Generic Medicines work-sharing initiative
- In 2021 we chaired the Access Consortium Biosimilars work-sharing initiative
- In 2021-22 we chaired the Access Consortium New Active Substances (NAS) work-sharing initiative, along with the COVID-19 Vaccines and Therapeutics Working Group (CVTWG).

In 2021-22, 12 submissions were approved through the NAS and 4 submissions were approved through the Access Generic Medicine Work-Sharing Initiative.

Project Orbis

Project Orbis is led by the US Food and Drug Administration (FDA) and provides a framework for concurrent submission and parallel review of oncology products among international partners, currently Australia (TGA), Canada (Health Canada), Switzerland (Swissmedic), Singapore (HSA),

Japan (PMDA) and Brazil (Anvisa). During 2021-22, 22 submissions were approved through Project Orbis.

International agreements and arrangements for Good Manufacturing Process (GMP) clearance

We have entered into various international agreements and arrangements with other countries and regulatory authorities to support international collaboration in the manufacturing of medicines. Some of these agreements and arrangements allow us to use inspections conducted by these regulatory authorities as part of the GMP clearance process in lieu of performing our own on-site inspection. Many regulatory authorities, including the TGA, are members of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), which is a non-binding, informal, cooperative arrangement between the authorities that regulate GMP for medicinal products.

International Medical Device Regulators Forum

Although only a medium sized regulator, we were one of the founding members of the International Medical Device Regulators Forum (IMDRF) in 2011 and very much helped shape IMDRF and its programs. IMDRF builds on the strong foundational work of the Global Harmonization Task Force on Medical Devices and aims to accelerate international medical device regulatory harmonisation and convergence to promote an efficient and effective medical devices sector.

During 2022 we chaired and operated the secretariat for IMDRF. As part of this role, we hosted 3 virtual IMDRF Management Committee meetings in January, April, and June 2022, and ran the hybrid IMDRF 22nd Management Committee Meetings in Sydney in September 2022. This is an important global event for the medical device industry and regulators with over 500 registrants from 41 countries expected to attend in-person or virtually, including representatives from 21 regulatory authorities. Standards for Health Software and Artificial Intelligence in Medical Devices were the focus for the industry stakeholder workshops in 2022.

We continued our leadership of the IMDRF Personalised Medical Devices (PMD) Working Group. The Group is responsible for developing guidance documents and recommendations for harmonising the regulation of PMDs. The work of the working group can be viewed on the IMDRF website.

3.1.3. Goal 3. Post-market global surveillance utilising international networks to monitor product safety and quality and maintain supply chains.

International Coalition of Medicines Regulatory Authorities Vaccine Pharmacovigilance Network

We continue to co-chair the International Coalition of Medicines Regulatory Authorities (ICMRA) COVID-19 Vaccine Pharmacovigilance Network (VPN) together with the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) which meets regularly to share knowledge, experience and communications on pharmacovigilance activities and the emerging benefit-risk profile of COVID-19 vaccines.

Throughout 2021-22, the ICMRA VPN focus was on 3 areas:

- facilitating internal and external communication of emerging safety signals
- collaborative action on Adverse Events of Special Interest (AESI) (including a simulation exercise)
- sharing information regarding AESI.

International collaboration in the VPN helped confirm several safety signals linked to COVID-19 vaccines and which regulatory actions were considered and implemented by regulatory agencies.

Managing supply chains

We have made improvements to medicine shortage data capabilities to enable more accurate forecasting of vulnerable medicine supply chains and have actively participated in the Global Regulators Working Group on Drug Shortages to exchange information on international medicine supply chains to manage and prevent important medicine shortages.

We have also worked across government, including with the Office of Supply Chain Resilience, (Department of Industry, Science and Resources) to share supply information and investigate potential vulnerabilities in Australia's medicine supply chains.

Our support enabled continued access to appropriate treatments during a shortage. Between July 2021 and June 2022, we:

- published 4 Serious Scarcity Substitution Instruments allowing community pharmacists to substitute specific medicines for a medicine in shortage, without prior approval from the prescriber
- approved the import and supply of 144 overseas alternative medicines under section 19A of the *Therapeutic Goods Act 1989* to maintain continuity of supply of medicines in shortage
- worked with health professional peak bodies to develop clinical advice to manage important shortages.

We have made improvements to medicine shortage reporting and management, increasing transparency and implementing new management initiatives. Improvements were finalised to the mandatory shortage online reporting form requiring sponsors to provide more accurate information about anticipated, current and resolved shortages and discontinuations. We also introduced a new function on the medicine shortage reports database, allowing users to download a .csv file of all current or archived shortages to improve transparency and searchability.

3.1.4. Goal 4. Strengthen regional regulatory capabilities for safer and effective therapeutics.

Pacific Medicines Testing Program

We participated in the Pacific Medicines Testing Program to assist participating Pacific Island Countries with access to Australian laboratory testing for therapeutic goods quality assurance.

2021 was the final year of the four-year Pacific Medicines Testing Program, which is funded by DFAT, with the program receiving a four-year extension until 2025 to continue its highly valued work with 13 Pacific countries. It now includes the ability to have COVID-19 products (such as face masks) and other medical devices tested.

The 2021-22 sample testing for the Pacific Medicines Testing Program received 26 samples from 9 participating countries.

The Indo-Pacific Regulatory Strengthening Program

The Program was launched in October 2018 and has the goal of increasing the availability of safe and effective medical products through improved regulatory practice and regional collaboration.

The Program incorporates 7 countries: Thailand, Vietnam, Laos, Cambodia, Papua New Guinea (PNG), Myanmar and Indonesia.

In 2022 we worked closely with the PNG regulator on the evaluation of a dossier supporting the registration of chloramphenicol, an antibiotic that is used for the treatment of typhoid and cholera. We performed a full evaluation, developed a report template in line with the ASEAN Common Technical Document requirements and delivered a series of virtual workshops to discuss the evaluation process and areas of concern.

We worked with the Cambodian Department of Drugs and Food to establish clear Good Manufacturing Practice guidelines and templates. Two in-country visits in 2022 allowed our team to work collaboratively with counterparts to draft an assessment checklist and associated guidance documents.

The online submission and workflow management software Integrated Regulatory Information Management System (IRIMS) has been successfully installed in Myanmar. IRIMS has been leveraged to triage and manage the submission queue. Support for select applications via videoconferences was made easier through the online registration system in between in-country missions.

The Food and Drug Department in Laos is concerned about management of a backlog of paper applications. We have been providing business process advice to assist with the implementation of strategies for backlog reduction and elimination, and to prevent a build-up in the future.

Case Study – Indo-Pacific Regulatory Strengthening Program

In partnership with DFAT, we hosted the first face-to-face meeting of the Indo-Pacific Regulatory Strengthening Program since 2019.

The Steering Committee and Forum was held on 4–5 May 2022 in Singapore and brought together the regulatory agencies from Thailand, Indonesia, Papua New Guinea (PNG), Cambodia, Laos, Myanmar, and Vietnam. Also attending were national malaria control program representatives from Laos and PNG, regulators from Pakistan and partners such as the World Health Organisation, United States Pharmacopeia, the Centre for Regulatory Excellence and Asia Pacific Leaders for Malaria Elimination.

As well as providing an opportunity for collaborating regulators to highlight their recent challenges and successes, this year's meeting covered 3 main themes: responding to the COVID-19 pandemic, strategies for malaria elimination, and regulatory reliance in action.

The Indonesian FDA gave an impressive presentation on how they have adapted their regulatory pathways to reduce COVID-19 vaccine evaluation time.

While COVID-19 has been all-consuming for the past 2 years, it is important not to neglect other infectious diseases prevalent in the region, such as malaria. Many partner countries are aiming to eliminate vivax malaria within the next 10-15 years, which is fast becoming a possibility with the approval and imminent roll out of the tafenoquine treatment, including the paediatric option recently approved by us. Dr Suchart from the Thai FDA also gave a presentation on how Thailand utilised technical support from us to approve tafenoquine in 2019, which allowed them to lead the ASEAN (Association of Southeast Asian Nations) joint assessment of tafenoquine with other countries in the region.

The Australian Expert Technical Assistance Program for Regional COVID-19 Vaccine Access – Regulatory Support and Safety Monitoring (AETEP-RSSM)

The AETAP-RSSM was launched to support access to high quality, safe and effective COVID-19 vaccines, and aims to provide coordinated and holistic Australian policy and regulatory expertise to national COVID-19 immunisation programs in Southeast Asia and the Pacific. The AETAP-RSSM commenced in April 2021 and incorporates 18 countries: Thailand, Vietnam, Laos, Cambodia, Papua New Guinea (PNG), Myanmar, Indonesia, Malaysia, the Philippines, Fiji, Samoa, Timor-Leste, Vanuatu, Tuvalu, Tonga, Kiribati, Solomon Islands and Nauru.

We supported Australian Government donations of COVID-19 vaccines across the region, under a pledge to share 60 million doses. This involved the provision of batch testing results, testing protocols, GMP certificates and licences, pre-market evaluation reports and scientific advice. When requested, data related to ongoing safety monitoring was also shared.

Data: Australian shared doses

Total shared doses

49,850,310

Country	Doses	Country	Doses
Global	114,400	Solomon Islands	618,200
Cambodia	2,830,530	The Philippines	7,132,080
Fiji	1,515,920	Timor-Leste	1,191,040
Indonesia	8,395,000	Thailand	452,790
Laos	1,504,780	Tonga	73,990
Nauru	19,300	Tuvalu	20,500
Kiribati	50,500	Vanuatu	160,000
Papua New Guinea	335,270	Vietnam	25,261,860
Samoa	175,150		

Table: COVID-19 vaccine doses shared from Australia's supply, procured by Australia, for partner countries or distributed through the COVAX Facility as at 18 October 2022.

Batch-specific documentation was provided for dozens of different batches, and technical assistance was provided to facilitate necessary regulatory approvals in Brunei, Indonesia, Vietnam, and PNG.

Priority 4 – Education and compliance

4.1. Industry compliance reforms

4.1.1. We monitored and enforced compliance, including the import, export, manufacture, supply, and advertising of therapeutic goods, imposing sanctions and penalties where necessary.

Monitoring and enforcement of compliance was actioned through analysis and review of complaints and reports received from the community, and advice from other regulators and agencies, including border and law enforcement agencies and state and territory regulators.

We prepared targeted education activities for wholesalers and suppliers within the vaping industry ahead of the changes to Nicotine Vaping Products in October 2021, and we developed specific educational materials in relation to the importation and supply of RATs (including parallel imports), to assist those new to the regulatory scheme to understand their obligations. Further education was required as many stakeholders had not previously had any retail need for obtaining and selling medical devices. For advertising-related compliance and enforcement outcomes and activities, please refer to our 2021-22 Advertising Compliance Annual Report.

We also monitored signals of non-compliance with Good Manufacturing Practice and used a risk-based approach to guide regulatory responses, investigating 235 signals of non-compliance for any impact of medicines supplied in Australia. We coordinated and managed recall actions for unsafe or defective therapeutic goods in the Australian market, as referenced earlier on page 12 of this report.

4.1.2. We undertook a review of the Therapeutic Goods Advertising Code 2021, which took effect on 1 January 2022.

We updated web guidance to reflect the changes to the Code and will continue to improve this content going forward, based on stakeholder feedback. Multiple webinars to help guide advertisers through the Code were hosted throughout 2021-22, highlighting the changes, and explaining the compliance obligations for advertisers during the transition period.

We released several upgraded advertising compliance tools to improve the experience for stakeholders submitting enquiries, reports, and applications, as well as internal improvements to how we manage this information. The upgrades include a new Advertising Compliance Application (AC App), a case management system which replaced the Advertising Management System. Improvements have also been made to the advertising forms on our website, including reports of non-compliance, application for approval to use a restricted representation in advertising, and other advertising enquiries.

4.1.3. We supported sponsors to understand their pharmacovigilance obligations and encouraged compliance through the Pharmacovigilance Inspection Program.

We operate the Pharmacovigilance Inspection Program to help sponsors maintain compliance with our requirements. In 2021-22 we evaluated Risk Management Plans Periodic Safety Update Reports, Summary Safety Reports for COVID-19 vaccines and products and operated the Pharmacovigilance Inspection Program to help sponsors maintain compliance with our requirements. Our pharmacovigilance inspectors conducted inspections, separate compliance investigations, issued infringement notices and reviewed enforceable undertakings[25].

[25] Please refer to Table 87 in Appendix 16.

4.1.4. We supported stakeholders in completing the transition to updated medicines labelling requirements.

A new version of the legislative instrument specifying advisory statements for certain medicines commenced on 1 January 2022. The Therapeutic Goods (Medicines Advisory Statements) Specification 2021 was made and follows several public consultations during 2021.

The Specification incorporates the Required Advisory Statements for Medicines Labels (RASML), which contains existing, and proposed, advisory label statements for relevant medicines. The Specification principally applies to over-the-counter medicines and registered complementary medicines and is designed to help ensure their safe and appropriate use. The updated RASML introduced new warning statement requirements for several medicines not previously covered by the RASML - those containing the active ingredients melatonin, menthol, methyl salicylate, mometasone and triptans. The Specification is intended to facilitate clarity in labelling requirements for sponsors.

4.1.5. We provided additional information for healthcare professionals to clarify regulatory requirements and application processes for certain devices.

We provided a comprehensive range of information including guidance documents, publications, frequently asked questions, and other resources for healthcare professionals, sponsors, manufacturers, and consumers relating to the regulatory and administrative requirements for including a medical device on the Australian Register of Therapeutic Goods (ARTG). This guidance was updated as required and addressed topics of relevance to the sector, such as "Using face masks in healthcare settings" and "Custom-made medical devices". In addition, we published instructions on our website for use of all COVID-19 RAT self-tests and required sponsors to have instructional videos and a helpline – to support consumers who purchased tests.

4.1.6. We continued to develop new ways to provide support and education to small-to-medium enterprises (SME), start-ups, researchers, and those unfamiliar with regulation through SME Assist.

SME Assist offers SMEs, researchers, start-ups and those unfamiliar with therapeutic goods regulation guidance to understand their regulatory and legislative obligations. We do this through workshops, webinars, interactive decision tools and podcasts. We published our first series of podcasts on 'Navigating Therapeutic Goods Regulation' which have resulted in hundreds of downloads. To effectively action and manage almost 60,000 enquiries during 2021-22 (an increase of 55% from enquiries pre-COVID-19), we introduced a new enquiry management system that allows our Customer Service operators to quickly interact with our Subject Matter Experts to provide consistent advice to external stakeholders.

4.1.7. To support patient safety, we managed restrictions to the advertising and supply of autologous cell and tissue therapies.

In July 2018, changes to the regulation of autologous hematopoietic cell transplantation (HCT) products in Australia prohibited consumer advertising of autologous human cell and tissue products and regulated the supply of autologous products that involve significant product processing.

During 2021-22 we received 7 reports alleging unlawful advertising of HCT therapies which resulted in 4 cases for further investigation. We removed over 100 products from a digital

platform where the advertising referenced plant extracts and claimed they had properties similar to "stem cells". We investigated one entity for this type of advertising and achieved voluntary compliance. Consistent with our Import, Advertising and Supply Compliance Priorities 2021-22, we are focusing on alleged unlawful advertisements which make claims about human cell and tissue products that relate to a serious disease or condition and are not substantiated by robust evidence.

4.2. Public safety education

4.2.1. We improved understanding of how therapeutic goods regulation is relevant to consumers, health professionals, and industry through the development of regulatory education materials, including tailored content resources, videos, infographics, webinars, podcasts, and other tools.

In 2021-22 we focused on significant stakeholder consultation, input, and education, with over 70 webinars and workshops covering a range of topics, including our extensive reform agenda and the commencement of new regulatory requirements for Software as a Medical Device and Personalised Medical Devices, along with patient information materials and up-classification of certain devices.

All the content we produce for social media aims to connect our work to audience needs. For example, our Vaccine Safety explainer video (which reached 95,000 people) educated viewers about using and understanding trusted sources of information about COVID-19 vaccine safety. We also ran an advertising campaign regarding medicinal cannabis access and regulation. The campaign targeted both consumers and health professionals and aimed to raise awareness of the options available regarding access to these products.

4.2.2. We educated consumers about counterfeit therapeutic goods through the publication of safety alerts and other education materials.

We provide information to consumers regarding counterfeit therapeutic goods through our publication safety alerts on our website.

In 2021-22 the alerts included:

- counterfeit Nitrile gloves
- counterfeit Somatropin Human Growth Hormone vials
- erectile dysfunction treatment claiming to contain herbal ingredients but also containing the undisclosed ingredient sildenafil
- hemp oil supplement that contained undisclosed amounts of cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC)
- a warning for consumers, advertisers, importers, and suppliers regarding counterfeit NVPs.

4.2.3. We provided awareness-raising activities to support adverse event reporting by consumers and health professionals, particularly for COVID-19 vaccines.

As part of a wider Department of Health communications program, we raised awareness of adverse event reporting channels and provided greater availability of services. This includes developing resources to educate the public about reporting an adverse event and increasing the operating hours of the NPS MedicineWise Adverse Medicine Events Line. There has been an increase in the number of vaccine adverse event reports received since before the COVID-19 vaccine rollout, particularly from consumers.

We educated consumers on the regulatory changes to NVPs that took effect from 1 October 2021. Following the 1 October 2021 scheduling reforms for nicotine, it is necessary for consumers to have a prescription from an Australian doctor to import or obtain NVPs. We undertook extensive work to educate all stakeholders about the reforms.

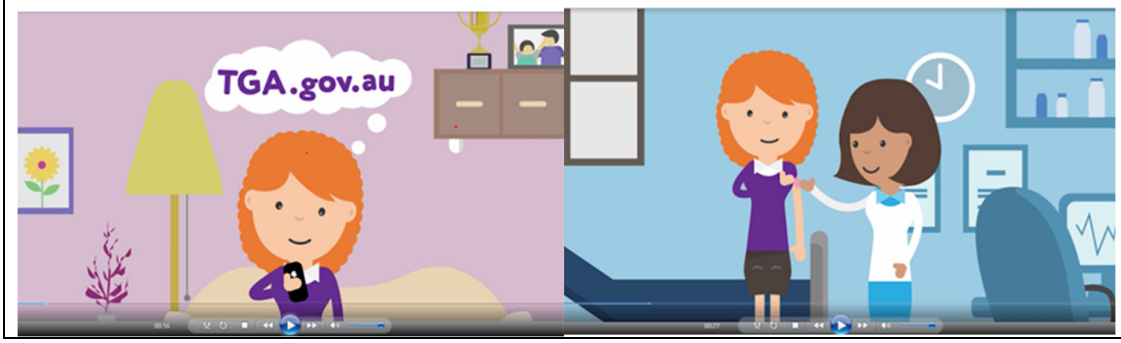
To help increase consumer awareness and understanding of the NVP changes, we launched an information and education campaign, targeted across various social media and search engines, along with General Practitioner practices and pharmacies. We worked with a range of stakeholders to tailor information to targeted audiences, including carers and those they care for, indigenous audiences and those from culturally and linguistically diverse backgrounds.

We also released fact sheets and a new video. The video was shared across our social media channels and is part of our national information and education campaign to ensure consumers and health professionals are aware of the new nicotine vaping requirements. One of the goals of the campaign is to encourage consumers to visit their GP to discuss quitting smoking. The Nicotine Vaping Products hub on our website contains further information and resources regarding the regulation of NVP.

Case Study – Adverse event information for COVID-19 vaccines

We developed a short video to help Australians understand the different adverse event information that we publish regarding the COVID-19 vaccines. The video highlights the difference between the unassessed reports of possible side effects provided on the Database of Adverse Events Notifications (DAEN) from the carefully assessed information we provide to the public in the COVID-19 vaccine safety report.

The video was an in-house production. It has been promoted on our social media channels and has been used in response to enquiries and misinformation received through these channels, as deemed appropriate.



4.2.4. We continued to undertake and publish the outcomes of listed medicine compliance reviews and educate consumers about the compliance review process.

During the reporting period we published the results of 78 listed medicine compliance reviews. The database provides consumers with compliance information relating to listed medicines that we have reviewed.

4.3. Access to information for Industry and Consumers

4.3.1. We provided exhibition booths at events to assist with providing up-to-date information on regulatory changes, and emerging issues and trends.

In 2021-22 we provided opportunities for industry and consumers to hear from and speak with us as many conferences and events. We presented and participated at seminars, exhibitions and conferences including:

- SME Assist Workshop – Supplying Personal Protective Equipment (July 2021)
- SME Assist Workshop – Meeting Your Obligations (August 2021)
- SME Assist Workshop - Supplying Medicinal Cannabis in Australia (October 2021)
- SME Assist Workshop - Flinders University (March 2022)
- SME Assist Workshop - Bridgetech (April 2022)
- Association of Regulatory and Clinical Scientists (ARCS) 2022 – Exhibition Booth (May 2022)
- AusMedtech – Exhibition Booth (May 2022)
- General Practice Conference & Exhibition – exhibition booth (May 2022).

We attended the ARCS Annual Conference in Sydney in May 2022 which is an example of our commitment to engage with our stakeholders. The conference brought together industry professionals, consumers, patients, practitioners, researchers, and academia to unite and educate. The Deputy Secretary provided a keynote address to the conference on 'How to improve patient outcomes through regulation in the digital world', while other staff updated attendees on the regulatory environment in Australia. We also had an exhibition booth at the conference.

Also, the Deputy Secretary and other senior executives of the TGA spoke at a wide range of other stakeholder events to discuss regulatory changes and emerging issues and trends. The Deputy Secretary spoke at over 50 national and international forums in 2021-22. Notable domestic ones included:

- Fortnightly/monthly COVID vaccine, treatment and testing updates for health professionals (July 2021- June 2022)
- Medicines repurposing forums (July 2021 and May 2022)
- Australian Industry Group (September 2021)
- Pharmacy Guild (July 2021 and March 2022)
- Theranostics national conference (September 2021)
- Deakin University/Geelong centre for Emerging Infectious diseases (November 2021)
- Medical Technology Association of Australia (November 2021)
- Royal Australasian College of Physicians (November 2021)
- Consumer Healthcare Products Australia (November 2021)
- High Blood Pressure Research Council (December 2021)
- Complementary Medicines Australia (December 2021)
- A-Cannabis (March 2022)

- Pathology Technology Australia (April 2022)
- Community Group presentations on COVID (May 2022)
- AusMedtech (May 2022)
- Generic Biosimilar Medicines Association (May 2022)
- National cannabis patient and healthcare professional conference (May 2022)
- Direct Selling Australia (May 2022).

4.3.2. We maintained our website to ensure that it is accessible, easy to navigate, accurate, and meets the needs of industry, health professionals and the general public, while working towards the development of a new website which was implemented in 2022-23.

We maintained our website to ensure that it is accessible, easy to navigate, accurate, and meets the needs of industry, health professionals, and the public, while working towards the development of a new website which was implemented in 2022-23.

Case Study – TGA Website Redevelopment Project

Through the TGA Website Redevelopment Project, our website was rebuilt to be a more modern portal for accessing information.

The project was informed by research which has shown our previous website:

- did not meet user or business needs
- acted as a barrier to communication, education, and compliance
- had content that is not understood by our users
- prevented users from completing common tasks.

The new website went live on 30 August 2022. This is just the first part, delivering:

- a cohesive experience and consistent user interface with familiar interaction and search patterns
- an improved and consolidated experience for databases and feed
- rewritten content that meets standards for Australian Government websites.

In the coming years, our new website will be integral to many of our transformation projects. In 2021-22, we published more than 1,900 updates (many related to COVID-19) on our website.

4.3.3. We expanded our education capability by partnering to enhance our engagement with consumers, health professionals, and industry stakeholders.

We worked with ANDHealth to deliver education activities about software medical devices through the ANDHealth and TGA partnership, with the first webinar held on 7 September 2021.

We also partnered with several organisations (the Federation of Ethnic Communities' Councils of Australia (FECCA), the National Aboriginal Community Controlled Health Organisation (NACCHO), Ninti One Ltd, and Carers Australia) to deliver an 8-week campaign informing consumers of the changes to nicotine vaping laws. These partnerships were crucial in targeting mainstream, Indigenous and Culturally and Linguistically Diverse (CALD) audiences. A total of 28 pieces of

content were developed for various platforms, reaching over 20 million people, and generating over 100,000 clicks through to the web content.

4.3.4. We informed and educated consumers, health professionals, and stakeholders on regulatory changes in priority areas through targeted digital communication campaigns and activities.

Throughout 2021-22 we delivered seven paid public education campaigns:

- NVPs – 1 October to 13 November 2021
- get vaccine safety information you can trust – 15 December 2021 to 15 January 2022
- changes to the application process for unapproved medicinal cannabis products – 17 December 2021 – 1 February 2022
- rapid antigen self-tests: advice on using saliva RATs – 7 February to 7 March 2022
- COVID-19 therapeutics – 4 March to 28 March 2022
- rapid antigen self-tests: buying compliant RATs – 25 March to 22 April 2022
- pathways to access unapproved medicinal cannabis products – 16 June to 30 June 2022.

The campaigns performed extremely well, reaching on average almost 1.7 million people per campaign, and achieving more than 3.6 million impressions per campaign (the number of times the content was displayed). A goal for the campaigns was to raise awareness among consumers and health professionals of priority education topics. This was measured through the CPR achieved – the Cost Per 1,000 people Reached. This demonstrates that the content was relevant and engaging to the target audiences. We also managed the unpaid activity on our social media accounts, including Facebook, Twitter, LinkedIn, Instagram, and YouTube, to maximise audience reach and ensure messages are distributed in channels used by consumers, health professionals, and other stakeholders.

4.3.5. We managed social media accounts, including Facebook, Twitter, LinkedIn, Instagram, and YouTube to maximise audience reach and ensure messages are distributed in channels used by consumers, health professionals, and other stakeholders.

We reached almost 20 million people through our series of 7 paid advertising campaigns on social media. Overall, our following recorded an increase in followers during the reporting period: Facebook +52%, Twitter +74%, Instagram +446% and LinkedIn +49%. Proactive campaigns contributed to these increases and helped ensure new audiences will be exposed to our posts in the future. We also produced and published over 100 videos (including recorded webinars).

Appendices

The appendices provide detailed statistical information on our performance during 2021-22.

1. Prescription Medicines

Applications to register new or vary existing prescription medicines are accompanied by supportive scientific data and evaluated, with timeframes underpinned by legislation and/or associated business rules.

The framework for prescription medicines includes the following categories which are subject to legislated and/or target timeframes:

Application category	Description	Timeframe in working days
Category 1	An application to register a new prescription medicine (other than an additional trade name) or to make a variation to an existing medicine that involves the evaluation of clinical, pre-clinical or bio-equivalence data. For example, new chemical entities, extensions of indication and new routes of administration.	Legislated timeframe: 40 working days for notification of whether the application has passed preliminary assessment and 255 working days for the completion of the evaluation and notification of the decision. For the priority review pathway, the target timeframe is 150 working days.
Comparable Overseas Regulator (COR) report-based process	An application accompanied by an un-redacted assessment report package from a comparable overseas regulator.	Legislated timeframe: 40 working days for notification of whether the application has passed preliminary assessment. The timeframe for completion of the evaluation and notification of the decision depends on the COR pathway: • COR-A[a]: 120 working days • COR-B[a]: 175 working days
Category 3	An application to register or to vary the registration of a prescription medicine where the application does not require the support of clinical, pre-clinical or bio-equivalence data. For example, broader changes to the product specifications, manufacturing and labelling or a change in trade name.	Legislated timeframe: 45 working days to notify the applicant of the decision.

[a] Under COR-A, the TGA regulatory decision will be based on a critical review of the COR assessment reports and an evaluation of the Australian label, Product Information (PI) and where required, the Risk Management Plan (RMP). Under the COR-B approach, the TGA regulatory decision will still be mostly based on a critical review of the COR assessment reports, and where required, the RMP.

Application category	Description	Timeframe in working days
Correction to, or completion of, a Register entry	An application to vary the registration of a prescription medicine to correct or complete information that was inadvertently recorded incorrectly or omitted from the Register entry. For example, errors to product information, or quality-related documentation.	No legislated timeframe: TGA processes as soon as possible.
Safety-related request	An application to vary the registration of a prescription medicine to either: • reduce the patient population that can receive the medicine or • add a warning or precaution.	No legislated timeframe: TGA processes as soon as possible.
Notification request to vary an ARTG entry	An application to vary the registration of a prescription medicine, where the application has been determined to pose a very low risk under certain conditions. For example, the removal of a redundant manufacture site.	No legislated timeframe: automatic approval on submission of e-form and full payment of fee.
Self-assessable request	An application to register or to vary the registration of a prescription medicine where the application: • does not require the support of clinical, pre-clinical or bio-equivalence data and • where no data are necessary or where the data can be self-assessed by the applicant. For example, certain changes to the pack size or approved product label.	Legislated timeframe: 45 working days for notification of acceptance or rejection of an application, completion of evaluation and notification of the decision.
Additional trade name	An application for an additional trade name for a registered prescription medicine.	Legislated timeframe: 45 working days.

1.1. Submission outcomes

Table 1 Number of completed prescription medicine submissions by type and outcome for July 2021 to June 2022

	Number			
Application Type	Approved	Withdrawn	Rejected	Total (% Approved)
Category 1				
A: New chemical entity/New biological entity/Biosimilar [a]	47	4	0	51 (92%)
B: New fixed-dose combination	3	0	0	3 (100%)
C: Extension of indication	56	5	0	61 (92%)
D: New generic medicine	82	20	0	102 (80%)
F: Major variation	40	2	0	42 (95%)
G: Minor variation [b]	3	0	0	3 (100%)
H: Minor variation [c]	12	0	0	12 (100%)
J: Changes to Product Information	95	1	0	97 (98%)
S: Provisional registration to full registration	4	0	0	4 (100%)
T: Provisional registration extension [T]	3	0	0	4 (100%)
Comparable Overseas Regulator (COR) – A				
A: New chemical entity/New biological entity/Biosimilar	2	0	0	2 (100%)
C: Extension of indication	2	0	0	2 (100%)
Comparable Overseas Regulator (COR) – B				
A: New chemical entity/New biological entity/Biosimilar	5	0	0	5 (100%)
B: New fixed-dose combination	1	0	0	1 (100%)
C: Extension of indication	1	0	0	1 (100%)
D: New generic medicine	4	0	0	4 (100%)
F: Major variation	1	0	0	1 (100%)
Minor Variations				
Category 3				
G: Minor variation [b]	61	7	0	68 (90%)
H: Minor variation [c]	1,483	32	0	1,515 (98%)
Correction [9D(1)]	233	9	0	242 (96%)
Additional trade name [ATN]	43	0	0	43 (100%)
Extension of Indications - Generic	24	1	0	25 (96%)
Internal Review	3	0	0	3 (100%)
Minor editorial change [MEC]	152	6	0	158 (96%)
Notification	1,621	16	0	1,637 (99%)
Self-assessable request [SAR]	634	20	1	0 (97%)
Safety-related request [SRR]	831	14	0	845 (98%)
Total	5,446	137	1	5,884 (98%)

[a] Includes submissions processed via the priority review.
[b] The type G minor variations differ from type H minor variations in that they result in a new ARTG entry.
[c] The minor variations (type H) refer to applications to change the formulation, composition or design specification or the

container for the goods or any other attribute that results in the goods being separate and distinct. These applications are typically 'Category 3' changes unless the supporting scientific package contains non-clinical or clinical data in which case the application is a 'Category 1' application.

In accordance with the legislation, registered medicines must comply with numerous standards at the time they are registered and throughout their lifecycle. Following an appropriate application and review of the scientific data and safety considerations, approval may be sought to supply a product when it does not meet a particular standard.

Table 2 Number of other prescription medicine applications

	2020-21	2021-22
	July to June	
Consent to supply/import/export when not conforming to a standard [S.14 and S.14A]	Number (% of Total)	
Approved	170 (100%)	94 (99%)
Rejected	0 (0%)	1 (1%)
Total (excluding withdrawals)	170 (100%)	95 (100%)

1.2.Approval times

Table 3 Prescription medicine application approval time for July 2021 to June 2022

Application type	Submissions Approved	Legislated timeframe	Approval time (TGA working days)		
			Mean	Median	Range
Category 1					
A: New chemical entity/New biological entity/Biosimilar [a]	44	255	174	191	23-151
B: New fixed-dose combination	3	255	198	196	193-206
C: Extension of indication [b]	53	255	184	198	39-253
D: New generic medicine	82	255	140	139	81-190
F: Major variation	40	255	159	170	8-227
G: Minor variation	3	255	185	184	161-209
H: Minor variation	12	255	178	186	58-236
J: Changes to Product Information requiring the evaluation of data	95	255	155	183	18-243
S: Provisional registration to full registration	2	N/A	217	217	179-254
T: Provisional registration extension	3	N/A	271	55	38-121
Comparable Overseas Regulator (COR-A)					
A: New chemical entity/New biological entity/Biosimilar [a]	2	120	115	115	112-117
C: Extension of indication [b]	2	120	105	105	91-118
Comparable Overseas Regulator (COR-B)					
A: New chemical entity/New biological entity/Biosimilar	5	175	145	141	122-166
B: New fixed-dose combination	1	175	160	160	160-160
C: Extension of indication	1	175	183	183	183-183
D: New generic medicine	4	175	117	110	105-145
F: Major variation	1	175	174	174	174-174

[a] Application type A figures do not include 3 submissions processed via the priority review pathway.
[b] Application type C figures do not include 3 submissions processed via the priority review pathway.

Table 4 Prescription medicine median approval time comparisons between 2020-21 and 2021-22

Application type	Legislated timeframe	Median approval time (TGA working days) 2020-21	2021-22 (% Change)
Category 1			
A: New chemical entity/New biological entity/Biosimilar [a]	255	195	191 (▼2%)
B: New fixed-dose combination	255	197	196 (▼1%)
C: Extension of indication [b]	255	194	198 (▲2%)
D: New generic medicine	255	148	139 (▼6%)
F: Major variation	255	170	170 (▼6%)
G: Minor variation	255	139	184(▲35%)
H: Minor variation	255	137	186 (▲35%)
J: Changes to Product Information requiring the evaluation of data	255	111	183 (▲66%)
Comparable Overseas Regulator (COR) – A			
A: New chemical entity/New biological entity/Biosimilar	120	167	115 (▼31%)
C: Extension of indication	120	97	105 (▲8%)
Comparable Overseas Regulator (COR) – B			
A: New chemical entity/New biological entity/Biosimilar	175	157	141 (▼10%)
C: Extension of indication	175	173	183 (▲6%)
D: New generic medicine	175	145	110 (▼24%)
Minor Variations			
Category 3			
G: Minor variation [c]	45	38	39 (▲3%)
H: Minor variation [d]	45	35	35 (▼0%)
Additional trade name [ATN]	45	18	35 (▲94%)
Extension of Indications - Generic	45	36	40 (▲10%)
Safety-related request [SRR]	N/A	33	37 (▲12%)
Self-assessable request [SAR]	45	36	32 (▼11%)
Minor editorial change [MEC]	45	32	33 (▲3%)
Correction [9D(1)]	N/A	173	42 (▼74%)

[a] Application type A figures do not include submissions processed via the priority review pathway.
[b] Application type C figures do not include submissions processed via the priority review pathway.
[c] The type G minor variations differ from type H minor variations in that they result in a new ARTG entry.
[d] The minor variations (type H) refer to applications to change the formulation, composition or design specification or the container for the goods or any other attribute that results in the goods being separate and distinct. These applications are typically 'Category 3' changes unless the supporting scientific package contains non-clinical or clinical data in which case the application is a 'Category 1' application.

Figure 1 Mean approval times (TGA working days) for submissions [a] by pathway 2020-21 and 2021-22

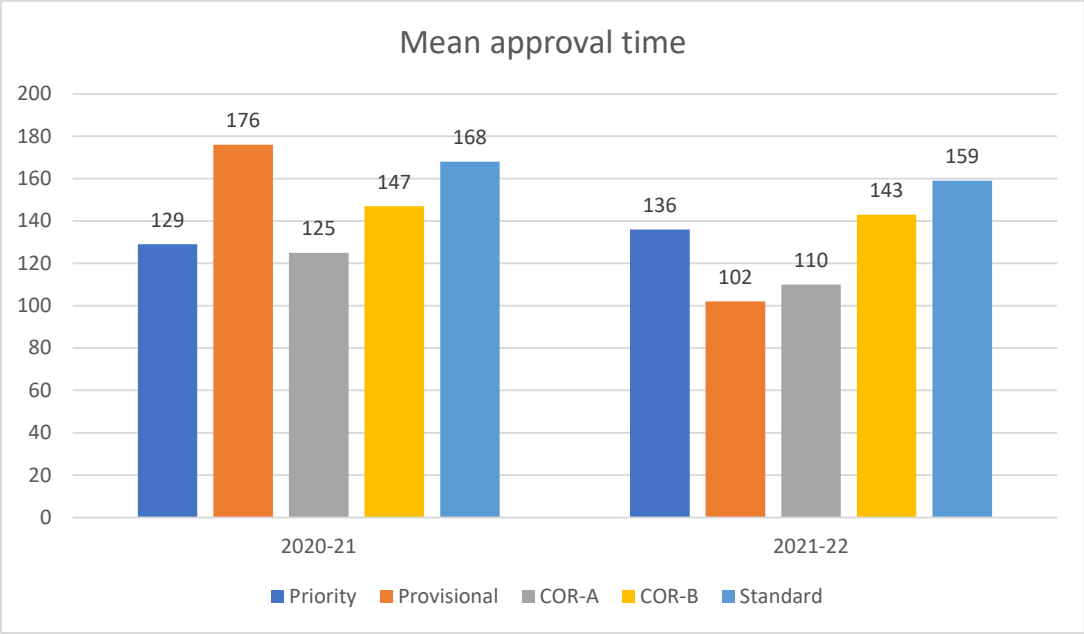
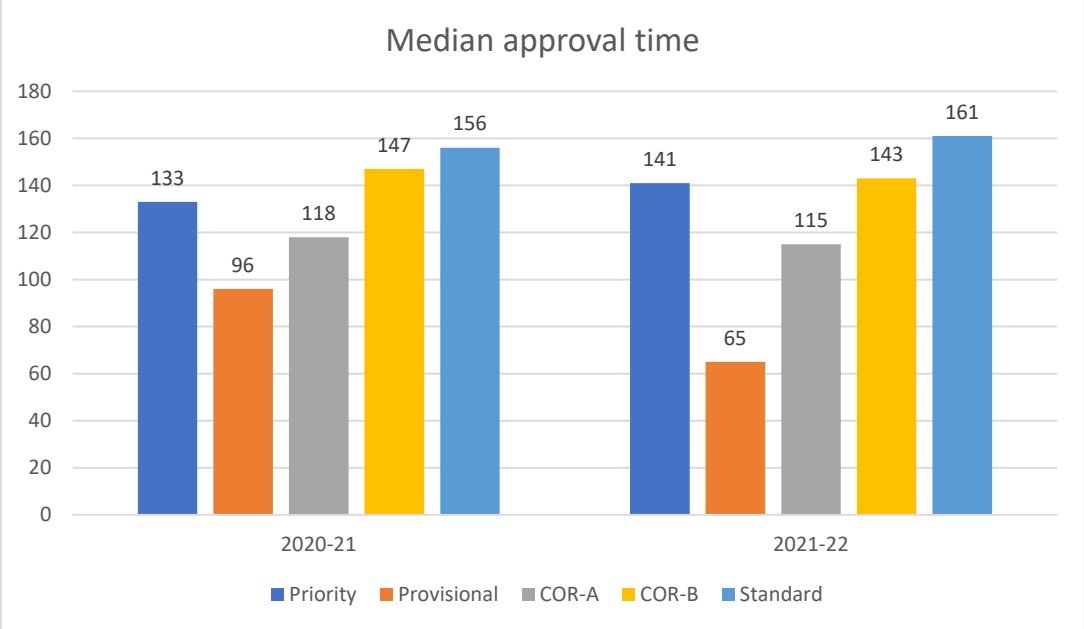


Figure 2 Median approval times (TGA working days) for submissions [a] by pathway 2020-21 and 2021-22



[a] For new chemical entities, new combinations, extension of indications, new generic medicines and major variations. During these periods, volumes of submission approvals for 2020-21 and 2021-22 were: standard - 223 and 202, priority review - 6 and 11, provisional approval - 10 and 6, COR-A - 2 and 0 and COR-B - 8 and 9, respectively.

1.3.Orphan drug designations

The objective of the orphan drug program is to provide an incentive to sponsors to bring medicines for a small population to market and make medicines available to Australian patients who may not otherwise be able to access them. The program incentive is a 100% waiver of TGA fees for application and registration. Designation is a formal process that allows us to make a decision regarding whether a medicine is eligible for orphan drug designation. This precedes the registration application. The eligibility criteria aim is to focus the program on the greatest unmet need. A prescription medicine must have a valid orphan drug designation at the time of application to be eligible for a waiver of application and evaluation fees.

Table 5 Number of orphan drug registrations

Orphan drug registrations and approval times quoted in Table 6 are also included in the total number of applications reported in each respective application category in the tables and figures below.

	2020-21		2021-22	
	July to June			
Application Type	Number Approved (% of Total)	Median approval time (TGA working days)	Number Approved (% of Total)	Median approval time (TGA working days)
A: New chemical entity/New biological entity/Biosimilar	15 (75%)	170	16 (70%)	163
C: Extension of indications	2 (10%)	111	6 (26%)	196
F: Major variation	3 (15%)	180	1 (4%)	174
Total	20 (100%)	172	23 (100%)	174

1.4.Priority review pathway

The priority review pathway supports patient access to vital and lifesaving prescription medicines months earlier than through the standard pathway. Priority review involves the same amount and type of evidence as the standard review process. The same standards for quality, safety and efficacy apply as under the standard process. The flexible approach we take on priority applications is much more resource intensive than the standard pathway. The pathway is reserved only for medicines that represent a major therapeutic advance. The determination process is used to assess whether a medicine is eligible for the priority pathway but does not necessarily mean that the medicine will be approved after evaluation and registered on the ARTG.

Table 6 Number of medicines approved through the priority review pathway [a]

	2020-21		2021-22	
	July to June			
Application Type	Number Approved (% of Total)	Median approval time (TGA working days)	Number Approved (% of Total)	Median approval time (TGA working days)
A: New chemical entity/New biological entity/Biosimilar	3 (36%)	123	3 (50%)	120
C: Extension of indications	7 (64%)	141	3 (50%)	147
Total	10 (100%)	133	6 (100%)	144

[a] The target timeframe for the priority review pathway is 150 working days.

1.5.Provisional approval pathway

The provisional approval pathway supports patient access to vital and lifesaving prescription medicines earlier than through the standard pathway. Time limited approval through the provisional pathway is based on the evaluation of preliminary clinical data where there is the potential for a substantial benefit to Australian patients. Knowledge of the risks and benefits of these medicines is less certain than for other approved prescription medicines. Provisional approval is granted for promising new medicines where we assess that the benefit of early availability of the medicine outweighs the risk inherent in the fact that additional data are still required.

A prescription medicine must have a valid provisional determination before it can be evaluated for registration under the provisional approval pathway. The determination process is used to assess whether a medicine is eligible for the provisional pathway but does not necessarily mean that the medicine will be approved after evaluation and provisionally registered on the ARTG.

Table 7 Number of provisional determinations granted

	2020-21		2021-22	
	July to June			
Application Type	Number Approved	Total Applications	Number Approved	Total Applications
Provisional Determination	18	19	29	29

Table 8 Provisional approval registrations

	2020-21		2021-22	
	July-June			
	Number Approved (% of total)	Median approval time (TGA working days)	Number Approved (% of total)	Median approval time (TGA working days)
Application type				
A: New chemical entity/New biological entity/Fixed dose combination	5 (83%)	136	13 (46%)	88
C: Extension of indications	0 (0%)	N/A	10 (36%)	54
F: Major variation	0 (0%)	N/A	4 (14%)	23
T: Provisional registration extension	1 (17%)	37	1 (4%)	121
Total	6 (100%)	96	28 (100%)	68

2. Over-the-Counter Medicines

Over-the-Counter (OTC) medicine applications are categorised as new medicine (N) or change (C) applications and are further categorised by risk (N1 and C1 are low risk, N5 and C4 are highest risk). The OTC application categorisation framework outlined on the following page defines the different OTC medicine application levels and the key application criteria.

Table 9 Categorisation of OTC medicine applications

Application category	Definition	Timeframe in days
N1	An application submitted as a 'clone'.	45 working days
N2	An application which complies with an OTC medicine monograph.	55 working days
N3	New application for a 'generic' medicine other than those 'generic' applications in levels N1, N2 or N4.	150 working days
N4	An application for a 'generic' medicine where the medicine: requires supporting safety and/or efficacy (clinical/toxicological) data or a justification for not providing such data; and/or requires a higher level of assessment due to the umbrella branding segment of the product name; and/or has not been previously registered as an OTC medicine following down-scheduling.	170 working days
N5	An application for a new product that is an extension to a 'generic category' product or an application for a product containing a new chemical entity as an active ingredient.	210 working days
CN	'Notification' changes, where their implementation would not impact the quality, safety or efficacy of a medicine. Includes quality and non-quality changes classified as 'negligible risk'.	N/A (Automated validation and approval)
C1	Quality and non-quality changes classified as 'negligible risk'.	20 working days
C2	Quality and non-quality changes classified as 'low risk' – no safety and/or efficacy data required; quality data may be required.	64 working days
C3	Quality and non-quality changes classified as 'low risk' – safety and/or efficacy data required unless justified; quality data may be required. Umbrella branding segment of new name requires a higher level of assessment.	120 working days
C4	Non-quality changes classified as 'moderate risk' – safety and/or efficacy data required unless justified.	170 working days
B1	Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that does not contain clinical data.	20 working days
B3	Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that contains clinical data or a justification as to why such data is not needed.	120 working days
Requests for consent under section 14/14A of the Act	Request for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard.	N/A

2.1.Approval times

We aim to have 80% of applications completed within target timeframes. The following target timeframes apply to OTC medicine applications:

Table 10 Median approval time for OTC medicine applications

	2020-21	2021-22
	July to June	
New medicine applications (days)		
N1	38	36
N2	37	28
N3	90	120
N4	126	163
N5	223	289
Change applications (days)		
C1	7	14
C2	40	24
C3	88	50
C4	318	0

Table 11 OTC medicine approval time against target time by application category July 2021 to June 2022

Application type	Number completed (% of Total)	Range	Mean	Median	% within target
New medicines					
N1	71 (36%)	0-127	38	36	65
N2	9 (5%)	2-50	26	28	100
N3	62 (32%)	26-206	119	120	74
N4	43 (22%)	63-295	174	163	56
N5	11 (6%)	134-311	267	289	18
Total	196 (100%)				
Change applications					
C1	278 (46%)	0-86	15	14	78
C2	300 (50%)	0-193	32	24	87
C3	20 (3%)	1-141	58	50	95
C4	0 (0%)	0	0	0	0
Total	598 (100%)				

2.2. Applications

2.2.1 New OTC medicine applications

Table 12 Applications received for new OTC medicines and changes to existing medicines

	2020-21	2021-22
	July to June	
	Number (% of Total)	
New medicine applications		
N1	107 (45%)	90 (46%)
N2	23 (10%)	21 (11%)
N3	71 (30%)	57 (29%)
N4	30 (13%)	25 (13%)
N5	5 (2%)	3 (2%)
Total	236 (100%)	196 (100%)
Change applications		
CN	128 (17%)	184 (23%)
C1	234 (32%)	315 (39%)
C2	349 (48%)	293 (36%)
C3	19 (3%)	11 (1%)
C4	1 (0.1%)	0 (0%)
Total	731 (100%)	803 (100%)

2.2.2 Completed applications

Table 13 New OTC medicine applications completed and outcomes

	2020-21	2021-22
	July to June	
	Number (% of Total)	
N1		
Approved	101 (94%)	71 (95%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	6 (6%)	4 (5%)
Returned/failed screening	0 (0%)	0 (0%)
Total	107 (100%)	75 (100%)
N2		
Approved	19 (83%)	9 (100%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	4 (17%)	0 (0%)
Returned/failed screening	0 (0%)	0 (0%)
Total	23 (100%)	9 (100%)
N3		
Approved	49 (73%)	62 (97%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	13 (19%)	2 (3%)
Returned/failed screening	5 (7%)	0 (0%)
Total	67 (100%)	64 (100%)
N4		
Approved	20 (83%)	41 (89%)
Rejected	0 (0%)	2 (4%)
Withdrawn by sponsor	2 (8%)	2 (4%)
Returned/failed screening	2 (8%)	1 (2%)
Total	24 (100%)	46 (100%)
N5		
Approved	8 (100%)	10 (59%)
Rejected	0 (0%)	1 (6%)
Withdrawn by sponsor	0 (0%)	3 (18%)
Returned/failed screening	0 (0%)	3 (18%)
Total	8 (100%)	17 (100%)

Table 14 OTC change applications completed and outcomes

	2020-21	2021-22
	July to June	
	Number (% of Total)	
C1		
Approved	212 (95%)	278 (98%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	12 (4%)	6 (2%)
Returned/failed screening	0 (0%)	0 (0%)
Total	224 (100%)	284 (100%)
C2		
Approved	350 (98%)	300 (93%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	7 (2%)	21 (7%)
Returned/failed screening	0 (0%)	0 (0%)
Total	357 (100%)	321 (100%)
C3		
Approved	4 (80%)	20 (95%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	1 (20%)	1 (5%)
Returned/failed screening	0 (0%)	0 (0%)
Total	5 (100%)	21 (100%)
C4		
Approved	6 (86%)	0 (0%)
Rejected	0 (0%)	0 (0%)
Withdrawn by sponsor	1 (14%)	1 (100%)
Returned/failed screening	0 (0%)	0 (0%)
Total	7 (100%)	1 (100%)

2.2.3 Other applications

Other application types that we process include requests for advice for the purpose of listing a medicine as a pharmaceutical benefit. In accordance with the legislation, registered goods must comply with numerous standards at the time they are registered and throughout their lifecycle. Following an appropriate application and review of the scientific data and safety considerations, we may grant an exemption from a particular standard for a product.

Table 15 Number of other OTC medicine applications

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Requests for advice for the purpose of listing a medicine as a pharmaceutical benefit		
Total	0	0
Requests for consent under section 14/14A of the Act to import, export or supply therapeutic goods not complying with an applicable standard		
Approved [a]	81 (99%)	13 (100%)
Rejected	1 (1%)	0 (0%)
Total	82 (100%)	13 (100%)

[a] This includes 49 requests for consent to supply products that do not comply with TGO92 only that was established as a temporary expedited process for sponsors adversely impacted by the COVID-19 pandemic.

3. Registered Complementary Medicines

Registered complementary medicines are considered to be of relatively higher risk than listed medicines based on their ingredients or the indications for the medicine. These medicines are fully evaluated by us for safety, efficacy, performance, and quality prior to being registered on the ARTG.

Table 16 Registered complementary medicine applications by outcome

	2020-21	2021-22
	July to June	
	Number (% of Total)	
New medicines		
Approved	9 (64%)	5 (50%)
Rejected	1 (7%)	2 (20%)
Withdrawn	4 (29)	3 (30%)
Returned/failed screening	0 (0%)	0 (0%)
Total	14 (100%)	10 (100%)
Variations		
Approved	71 (100%)	21 (75%)
Rejected	0 (0%)	1 (4%)
Withdrawn	0 (0%)	6 (21%)
Returned/failed screening	0 (0%)	0 (0%)
Total variations completed	71 (100%)	28 (100%)
Application for consent under section 14/14A of the Act to import, export or supply therapeutic goods not complying with an applicable standard		
Approved	4 (100%)	2 (67%)
Rejected	0 (0%)	0 (0%)
Withdrawn	0 (0%)	1 (33%)
Total	4 (100%)	3 (100%)

4. Assessed Listed Medicines

Assessed listed medicines are considered to be of slightly higher risk than listed medicines based on their indications, but not as high risk as registered medicines. Because assessed listed medicines carry intermediate risk indications, they are fully evaluated by us for efficacy before listing in the ARTG.

Assessed listed medicine applications are categorised as new medicine ('L(A)') or change (C) applications. The application levels are outlined in Table 19.

Table 17 Categorisation of assessed listed medicine applications

Application category	Definition	Evaluation timeframe (legislated)
L(A)1	Medicines that are identical to an existing assessed listed medicine other than permitted differences, such as its name, colour, printing ink, flavour and/or fragrance.	45 working days
L(A)2	Generic medicines or medicines where a Comparable Overseas Body (COB) has demonstrated their efficacy.	60 working days
L(A)3	Medicines that are not covered by L(A)1 or L(A)2; and require an independent evaluation of their efficacy; or for an existing assessed listed medicine, contain a different active ingredient, indication, dosage form, strength, or excipient.	150 working days
L(A)CN	'Notification' changes, where their implementation would not affect the established efficacy of the medicine.	N/A
L(A)C1	Changes to the medicine label and ARTG entry that do not affect the efficacy of the medicine.	30 working days
L(A)C2	Changes that may affect the efficacy of the medicine.	120 working days

Table 18 Assessed listed medicine applications by outcome

	2020-21	2021-22
	July to June	
	Number (% of Total)	
New medicines		
Approved	2 (67%)	0 (0%)
Refused	1 (33%)	1 (100%)
Withdrawn	0 (0%)	0 (0%)
Failed screening	0 (0%)	0 (0%)
Total	3 (100%)	1 (100%)

Table 19 Applications received for new Assessed listed medicines and changes to existing medicines

	2020-21	2021-22
	July to June	
	Number (% of Total)	
New medicine applications		
L(A)1	0 (0%)	0 (0%)
L(A)2	0 (0%)	0 (0%)
L(A)3	1 (100%)	2 (100%)
Total	1 (100%)	2 (100%)
Change applications		
CN	0 (0%)	0 (0%)
C1	1 (100%)	1 (100%)
C2	0 (0%)	0 (0%)
Total	1 (100%)	1 (100%)

5. Listed Medicines

Listed medicines are considered to be of relatively lower risk than other medicines on the basis that they can only contain pre-approved ingredients and indications. Unlike registered medicines, we do not assess each listed medicine before it goes onto the market. However, we do require sponsors to certify that the medicine complies with all relevant legislation, and that they hold evidence at the time of listing (and at all times) that their medicine does what it says it will.

We may select a listed medicine for a post-market review where we require the sponsor to provide evidence of compliance with regulatory requirements. This includes the assessment of compliance with standards, efficacy, labelling and advertising. If we find that the medicine does not comply with all applicable regulatory requirements, the medicine's listing may be suspended or cancelled.

5.1.New ingredients permitted for use in listed medicines

Table 20 New listed medicine ingredient applications by outcome

	2020-21	2021-22
	July to June	
Application outcome		
Approved	5 (38%)	14 (56%)
Rejected	3 (23%)	4 (16%)
Withdrawn	5 (38%)	7 (28%)
Returned/failed screening	0 (0%)	0 (0%)
Total completed	13 (100%)	25 (100%)

5.2. Indications permitted for use in listed medicines

Table 21 Permitted indication applications by outcome

	2020-21	2021-22
	July to June	
Application outcome		
Approved	3 (43%)	0 (0%)
Rejected	3 (43%)	3 (75%)
Withdrawn	1 (14%)	1 (25%)
Total completed	7 (100%)	4 (100%)

5.3. New listed medicines

Table 22 New listed medicines

	2020-21	2021-22
	July to June	
New listed medicines	2,184	1,929

5.4. Variations

Table 23 Listed medicine variations under subsection 9D(1) of the Act

Subsection 9D(1) of the *Therapeutic Goods Act 1989* provides for variations to be made to an entry on the ARTG where information included on the ARTG is incomplete or incorrect. These variations are considered by a delegate. Other types of variations to listed medicines are applied for and processed automatically by the online application system.

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Medicine variation		
Approved	142 (88%)	178 (88%)
Rejected	2 (1%)	0 (0%)
Withdrawn	18 (11%)	24 (12%)
Total	162 (100%)	202 (100%)

5.5. Post-market applications

Table 24 Listed medicine post-market applications

After listing, it may be necessary for the TGA to consider an application to support compliance with various requirements. The TGA receives applications for consents under sections 14 and 14A of the Act (which provides consent to import, supply or export therapeutic goods that do not comply with applicable standards). Additionally, some listed medicines require pre-clearance, in order to supply a batch of medicine that contains ingredients that are at risk of containing aristolochic acids (which is a toxic substance). The TGA also receives applications under subsection 7(2) of the Act, to declare whether a type of product is/is not a therapeutic good under section 7 of the Act.

	2020-21	2021-22
	July to June	
Applications Assessed		
Aristolochic Acid clearances		
Approved	40	45
Rejected	2	2
Total number of clearances	42	47
Consents under section 14/14A of the Act		
Approved	31	5
Extensions [a]	0	582
Rejected	4	1
Withdrawn	1	0
Total number of consents	36	588
Section 7 declaration		
Approved	0	0
Rejected	1	1
Withdrawn	0	0
Total number of declarations	1	1
Total completed	79	636

[a] Section 14 extensions were given to products that already held a consent to supply goods that did not comply with Section 9(2) of the Therapeutic Goods Order 92 – Labelling that was due to expire in September 2021.

Table 25 Conditions of listing

The TGA may impose additional conditions of listing on products after listing. Some of these apply to all listed medicines and are automatically applied at the time of listing, while some only apply to certain products and these sponsors are notified after their products are listed in the ARTG. Currently the product-specific conditions of listing are imposed on listed medicines that contain plant species that look very similar or have a name that sounds very similar to plant species that are likely to contain aristolochic acids, as well as on sunscreen products to ensure they have appropriate SPF testing data following issues with AMA laboratories.

	2020-21	2021-22
	July to June	
Product specific conditions of listing		
Aristolochic Acid	27	3
Sunscreens [a b]	818	296
Total	845	299

[a] Letter sent to all sponsors in the ARTG when the new condition was imposed
[b] Letter only sent to new sunscreen listings in this period

5.6. Enquiries and education activities

Table 26 Enquiries and education

The TGA responds to stakeholder enquiries related to the regulation of listed medicines, including Food Medicine Interface (FMI) and Cosmetic Medicine Interface (CMI) enquires. To help address frequently asked questions or areas where consistent compliance issues are observed in listed medicines, the TGA provides educational presentations for external stakeholders (e.g., at conferences and seminars) and fact sheets for FMI/CMI issues. The TGA also responds to listed medicine-related enquiries related to educational information sent to stakeholders.

	2020-21	2021-22
	July to June	
Enquiries and education actions		
General enquiries about non-prescription medicines (OTC, listed medicines, Registered Complementary medicines)- emails	4,826	3,648
General enquiries about non-prescription medicines (OTC, listed medicines, Registered Complementary medicines)- emails – phone calls	843	627
FMI/CMI related enquires	25	33
Guidelines, media releases, factsheets, educational web content, social media posts [a]	N/A	13
FMI/CMI educational correspondences (e.g. follow up on fact-sheet) [a]	N/A	4

[a] data unavailable or process was not in existence

5.7. Food/Cosmetic-Medicine Interface activities

Table 27 Food Medicine Interface (FMI) and Cosmetic Medicine Interface (CMI) assessments

FMI/CMI referrals may come from internal and external stakeholders. Some externals stakeholders include Food Standards Australia New Zealand and the state and territory food regulators, the Australian Border Force, and the Australian Federal Police. Referrals are also received through consumers and industry members. All referrals are triaged based on risk to consumers.

	2020-21	2021-22
	July to June	
FMI/CMI assessments		
FMI/CMI referrals triaged and queued	63	60
FMI/CMI referrals triaged and closed via factsheet [a] [b]	N/A	8
Completed FMI/CMI assessments	47	38
Referral to another TGA area or government organisation	44	32

[a] Using factsheet developed in Table 26
[b] data unavailable or process was not in existence

5.8. Compliance and enforcement

Signals of non-compliance related to listed medicines that are handled by the TGA mainly include complaints and referrals from external or internal stakeholders and weekly scanning of recently listed medicines on the ARTG. The ARTG scanning allows the detection of potential non-compliance of a medicine prior to the sponsor marketing the medicine. Early engagement with the sponsor soon after their listing also allows sponsors to update their product before they suffer commercial losses.

Signals of potential non-compliance are triaged and assessed for alleged breaches, and actions taken are dependent on the risks posed. Actions from signals can include low level compliance actions such as an educational correspondence, or an in-depth investigation may be conducted that may result in medium to high level compliance or enforcement actions such as a warning letter, a compliance review or infringement notices.

Targeted compliance reviews may be initiated as a result of signals investigations or from intel/data that is available regarding a compliance topic. When issues identified in a signal investigation is found to be of high risk, a compliance review will be triggered to conduct a more in-depth investigation and/or take further enforcement action.

A compliance review will result in one of the following outcomes:

- no compliance breaches are identified against selected listing requirements, the review is concluded, and the medicine remains on the ARTG
- compliance breaches are identified for the selected listing requirements
- the review is not completed as the sponsor has cancelled the medicine
- the review is closed due to the unavailability of information in determining its compliance status as the medicine is yet to be manufactured.

The TGA publishes results of listed medicine compliance reviews on the TGA website to assist consumers to make informed choices about whether a listed medicine is appropriate for them.

The 2021-22 compliance strategy for listed medicines mainly included targeted compliance activities based on intel/data. In the future, more random reviews (random selection of listed medicines for audit) will be used to assess the impact of our targeted strategy to measure compliance rates more broadly.

Table 28 Signals triaging and investigations

	2020-21	2021-22
	July to June	
Signals monitored		
Newly listed medicines monitored	1,947	2,115
Leads (complaints and referrals) received	54	42
Signals of non-compliance risk assessed and investigated [a]	78	221
Signals of non-compliance resolved through low to medium level compliance actions [b] (% success [c])	54 [d]	41 (53%)
Signals of non-compliance transitioned to a compliance review	21	19

[a] This process changed between the 2020-21 and 2021-22 financial years. In 2020/21, all flagged signals were investigated, whereas in 2021/22, flagged signals were risk assessed to determine whether an investigation is warranted, while lower risk signals were logged for monitoring.

[b] E.g. obligations notice or educational correspondence

[c] Success is measured as a percentage of medicines brought into compliance voluntarily by sponsors after receiving a low to medium level compliance action

[d] Process for checking effectiveness of these actions in bringing about compliance commenced in March 2022, as such data unavailable for 2020/21.

Table 29 Listed medicine compliance reviews by type

	2020-21	2021-22
	July to June	
Initiated reviews		
Compliance reviews	70	52
Compliance reviews transitioned from signal investigations	30	19
Total number of initiated reviews	100	71
Reviews on hand	133	140
Completed reviews		
Compliance reviews	40	49
Compliance reviews transitioned from signal investigations	36	29
Total number of completed reviews	76	78

Table 30 Compliance and enforcement actions

	2020-21	2021-22
	July to June	
Compliance and enforcement actions		
Cease review notices	33	6
Conclusion notices	7	19
Educational correspondence (e.g. obligations notices, educational emails)	43	91
Deficiencies notices	8	13
Warning notices (cease and desist)	11	6
Proposal to cancel notices	30	28
Cancellation notices	5	2
Directions/Prevention notice	0	1
Infringement notices	9	6
Published outcomes of compliance reviews	84	78
Referral to another TGA area or government organisation	6	17
Total actions undertaken [a]	237	270

[a] An investigation or review may give rise to more than one action

Table 31 All compliance review [a] outcomes

	2020-21	2021-22
	July to June	
Compliance status determined		
Medicines with no compliance breaches	6	21
Medicines with verified compliance breaches:	39	50
Medicine no longer on the ARTG		
Cancelled by the TGA	4	3
Cancelled by the sponsor after being notified of the compliance breaches	19	23
Medicine remains on the ARTG		
Compliance breaches addressed after low level compliance action [b]	6	14
Compliance breaches addressed after proposal to cancel	10	10
Sub-total	45	71
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	23	7
Medicines not yet manufactured	8	0
Sub-total	31	7
Product is not a therapeutic good	0	0
Total completed	76	78

[a] All compliance reviews, including those that transitioned from signal investigations

[b] E.g., deficiencies/obligations/warning notices

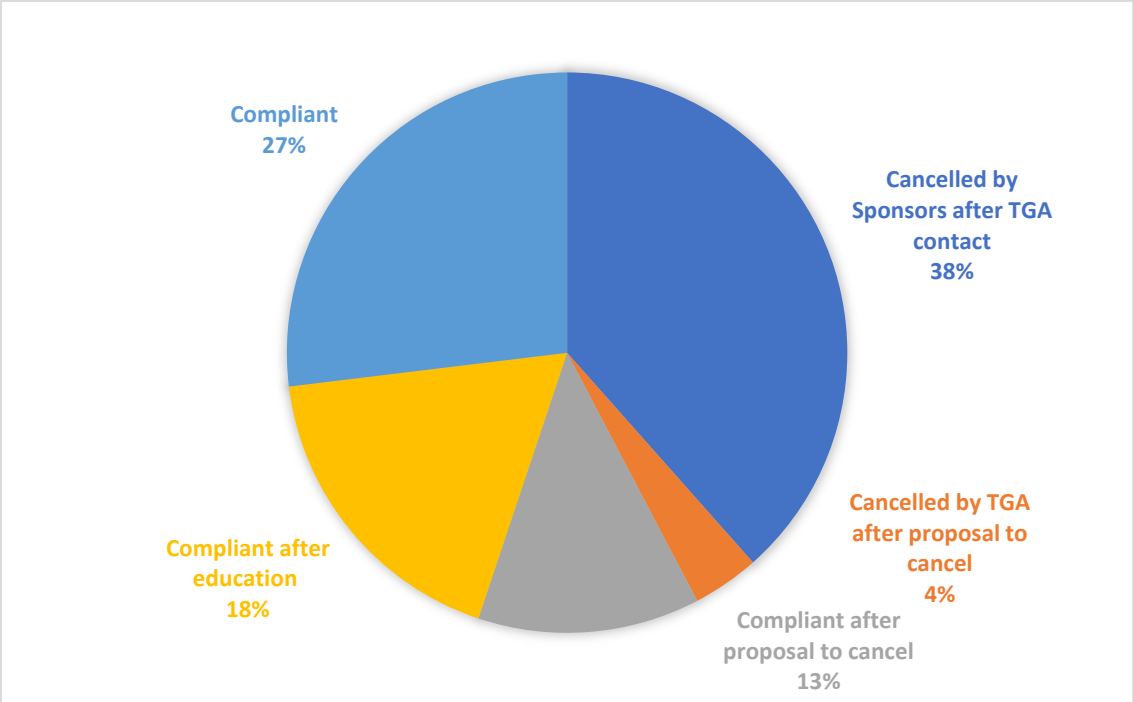
Table 32 Reach of compliance activities for listed medicines

In this table, compliance interactions include letters such as obligations notices, deficiency notices as well as other educational correspondences such as targeted educational email campaigns and direct email communications with sponsors. Compliance interactions includes all activities conducted for listed medicines, from applications and applying conditions of listing, through to signal investigations and compliance reviews.

Indirect reach of our compliance activities such as through reading media releases, publication of compliance review outcomes, publication of infringement/prevention notices have not been captured here.

	2020-21	2021-22
	July to June	
Sponsors reached		
Sponsors who received any compliance interactions	247 (10%)	226 (10%)
Listings covered by any compliance interactions	1509 (14%)	609 (5%)

Figure 3 [a] Outcomes of completed compliance reviews



[a] A significant proportion of listed medicine reviews are concluded after the sponsor has adequately addressed the compliance breaches identified by us. Under the *Therapeutic Goods Act 1989* sponsors are given an opportunity to respond to issues raised during a compliance review.

Figure 3 Outcomes of completed compliance reviews	Count	Percentage
Cancelled by Sponsors after TGA contact	30	38%
Cancelled by TGA after proposal to cancel	3	4%
Compliant after proposal to cancel	10	13%
Compliant after education	14	18%
Compliant	21	27%
Total	**78**	**100%**

Types of listed medicine compliance issues identified

The following is a summary of the types of issues identified in the completed compliance activities (signals investigations and compliance reviews). Each review or investigation of a medicines may identify multiple issues. Compliance reviews can be further divided into 2 categories, whether they are triggered by signals investigations or not. When issues identified in a signal investigation is found to be of high risk, a compliance review will be triggered to conduct a more in-depth investigation and/or take further enforcement action.

Table 33 Issues identified in compliance reviews (excluding compliance reviews transitioned from signals investigations)

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Type of compliance issue		
Information provided in ARTG entry [a]	2 (4%)	4 (11%)
Manufacturing, quality and/or formulation	3 (6%)	6 (16%)
Labelling	15 (31%)	9 (24%)
Advertising	14 (29%)	9 (24%)
Unacceptable presentation [b]	0 (0%)	3 (7%)
Evidence [c]	12 (25%)	4 (11%)
Safety [d]	0 (0%)	0 (0%)
Non-response to a request for information [e]	0 (0%)	0 (0%)
Other [f]	2 (4%)	3 (7%)
Total	48 (100%)	38 (100%)

[a] 'ARTG information' broadly refers to situations where the information on the ARTG is incorrect, including indications that are not eligible for listing and ingredients that do not comply with listing requirements.

[b] 'Unacceptable presentation' means that aspects such as name, labelling, packaging, advertising or other material state or suggest that the medicine has ingredients, components or characteristics that it does not have.

[c] 'Evidence' means the evidence held by the sponsor does not support the claims relating to the medicine.

[d] 'Safety' means that the medicine is not safe for the purposes for which it is to be used.

[e] In previous reports 'other' included non-response to a request for information. However, this is now being reported separately.

[f] 'Other' compliance issues may include the sponsor failing to comply with a condition that the medicine is subject to.

Table 34 Issues identified in compliance reviews transitioned from signals investigations

	2020-21	2021-22
	July to June	
	Number (% of Total)*	
Type of compliance issue		
Information provided in ARTG entry [a]	10 (29%)	13 (29%)
Manufacturing, quality and/or formulation	0 (0%)	6 (13%)
Labelling	12 (35%)	15 (33%)
Advertising	10 (29%)	7 (16%)
Unacceptable presentation [b]	1 (3%)	3 (7%)
Evidence [c]	1 (3%)	0 (0%)
Safety [d]	0 (0%)	0 (0%)
Non-response to a request for information [e]	0 (0%)	0 (0%)
Other [f]	0 (0%)	1 (2%)
Total	34 (100%)	45 (100%)

[a] 'ARTG information' broadly refers to situations where the information on the ARTG is incorrect, including indications that are not eligible for listing and ingredients that do not comply with listing requirements.
[b] 'Unacceptable presentation' means that aspects such as name, labelling, packaging, advertising or other material state or suggest that the medicine has ingredients, components or characteristics that it does not have.
[c] 'Evidence' means the evidence held by the sponsor does not support the claims relating to the medicine.
[d] 'Safety' means that the medicine is not safe for the purposes for which it is to be used.
[e] In previous reports 'other' included non-response to a request for information. However, this is now being reported separately.
[f] 'Other' compliance issues may include the sponsor failing to comply with a condition that the medicine is subject to.
*all percentages have been rounded up

Table 35 Issues identified in signals investigations (i.e., fully investigated signals that did not transition to compliance reviews)

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Type of compliance issue		
Information provided in ARTG entry [a]	18 (12%)	49 (31%)
Manufacturing, quality and/or formulation	18 (12%)	5 (3%)
Labelling	20 (14%)	23 (15%)
Advertising	67 (45%)	56 (35%)
Evidence [b]	10 (7%)	12 (8%)
Safety [c]	10 (7%)	7 (4%)
Other [d]	4 (3%)	6 (4%)
Total	147 (100%)	158 (100%)

[a] 'ARTG information' broadly refers to situations where the information on the ARTG is incorrect, including indications that are not eligible for listing and ingredients that do not comply with listing requirements.
[b] 'Evidence' means the evidence held by the sponsor does not support the claims relating to the medicine.
[c] 'Safety' means that the medicine is not safe for the purposes for which it is to be used.
[d] 'Other' compliance issues may include the sponsor failing to comply with a condition that the medicine is subject to.
*all percentages have been rounded up/down

Figure 4 Types of compliance issues identified by reason for initiation

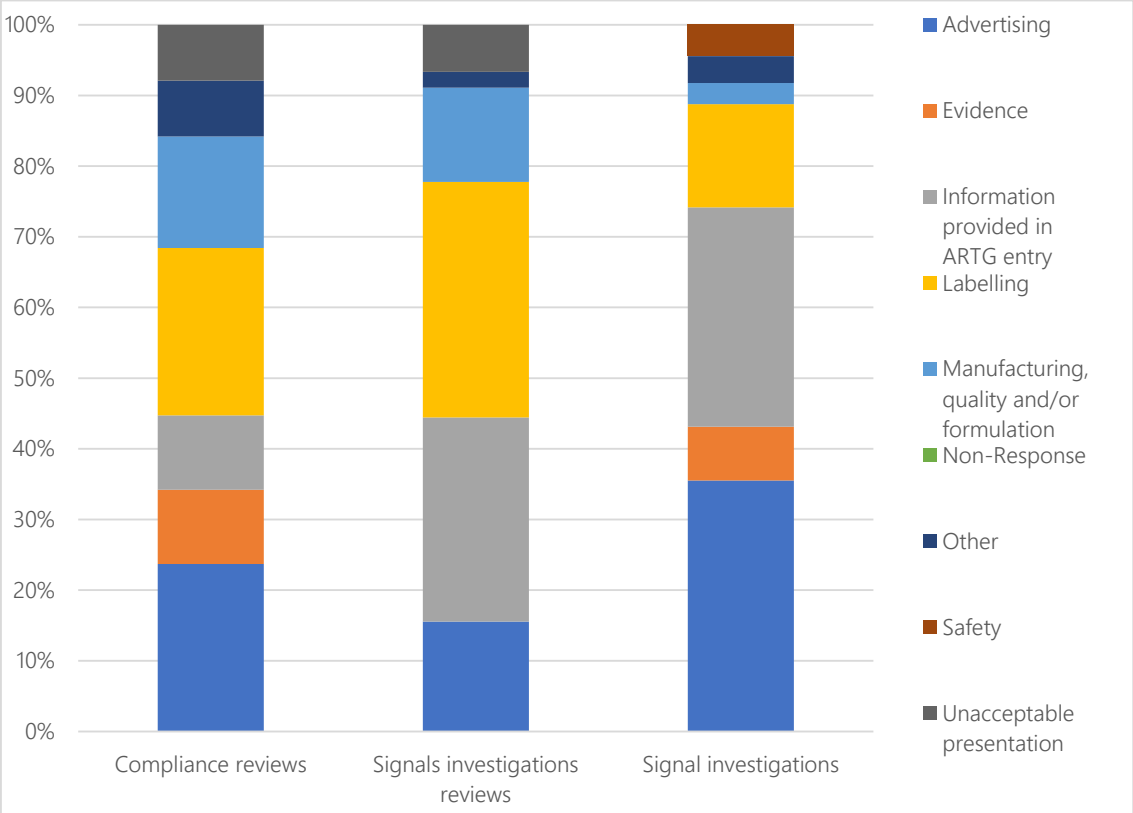


Figure 4 Types of compliance issues identified by reason for initiation	Compliance reviews	Signals investigations reviews[a]	Signal investigations
Advertising	9 (23%)	7 (16%)	56 (35%)
Evidence	4 (11%)	0 (0%)	12 (8%)
Information provided in ARTG entry	4 (11%)	13 (29%)	49 (31%)
Labelling	9 (23%)	15 (33%)	23 (15%)
Manufacturing, quality and/or formulation	6 (16%)	6 (13%	5 (3%)
Non-Response	0 (0%)	0 (0%)	0 (0%)
Other	3 (8%)	1 (2%)	6 (4%)
Safety	0 (0%)	0 (0%)	7 (4%)
Unacceptable presentation	3 (8%)	3 (7%)	0 (0%)
Total	**38 (100%)**	**45 (100%)**	**158 (100%)**

[a] Compliance reviews transitioned from signal investigations

6. Biologicals and Blood Components

6.1.Inclusion of biologicals

Table 36 Applications for biologicals [a] and blood received and on hand

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Applications received		
Technical Master File (TMF)[b] new	0 (0%)	0 (0%)
TMF annual updates	3 (5%)	3 (3%)
TMF variations	7 (12%)	6 (6%)
TMF notifications	7 (12%)	5 (5%)
Plasma Master File [c] annual updates	14 (25%)	12 (11%)
Biological Class 1 – new applications	2 (4%)	1 (1%)
Biological Class 2 – new applications	5 (9%)	5 (5%)
Biological Class 3 – new applications	0 (0%)	0 (0%)
Biological Class 4 – new applications	4 (7%)	3 (3%)
Biological Class 2 – variations	8 (14%)	24 (23%)
Biological Class 3 – variations	1 (2%)	10 (10%)
Biological Class 4 – variations	6 (10%)	35 (33%)
Total received	57 (100%)	104 (100%)
Applications on hand		
TMF new	0 (0%)	0 (0%)
TMF annual updates	1 (5%)	1 (4%)
TMF variations	2 (10%)	2 (9%)
TMF notifications	1 (5%)	1 (4%)
Plasma Master File annual updates	6 (30%)	2 (9%)
Biological Class 1 – new applications	0 (0%)	0 (0%)
Biological Class 2 – new applications	5 (25%)	3 (14%)
Biological Class 3 – new applications	0 (0%)	0 (0%)
Biological Class 4 – new applications	2 (10%)	3 (14%)
Biological Class 2 – variations	3 (15%)	5 (18%)
Biological Class 3 – variations	0 (0%)	3 (14%)
Biological Class 4 – variations	0 (0%)	3 (14%)
Total on hand	20 (100%)	23 (100%)

[a] The *Australian Regulatory Guidelines for Biologicals* (published on our website) define the different biological classes.

[b] Technical Master Files (TMF) contain information from manufacturers that demonstrate how product safety and quality standards have been met for Blood, Blood Components and Haematopoietic Progenitor Cells.

[c] Plasma Master Files contain control strategies that ensure the quality and safety of plasma, from collection through to plasma pooling prior to fractionation and including donor selection criteria and testing, which are part of medicinal products or medical devices.

Table 37 Completed applications for biologicals and blood

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Biologicals applications		
Technical Master File (TMF) new	0 (0%)	0 (0%)
TMF annual updates	3 (5%)	3 (3%)
TMF variations	6 (10%)	4 (4%)
TMF notifications	8 (14%)	4 (4%)
Plasma Master File annual updates	8 (14%)	10 (11%)
Biological Class 1 – new applications	2 (4%)	1 (1%)
Biological Class 2 – new applications	1 (2%)	2 (2%)
Biological Class 3 – new applications	1 (2%)	0 (0%)
Biological Class 4 – new applications	2 (4%)	1 (1%)
Biological Class 2 – variations	14 (24%)	19 (22%)
Biological Class 3 – variations	2 (4%)	12 (13%)
Biological Class 4 – variations	10 (17%)	35 (39%)
Total completed	57 (100%)	91 (100%)

7. Medicine and Vaccine Adverse Event Reports

7.1. Adverse medicine and vaccine reaction notifications

Table 38 Source of notifications of medicine and vaccine adverse reactions [a]

	2020-21	2021-22
	July to June	
Received		
Mean number of reports received weekly	1,174	2,421
Vaccine reports	41,586	107,958
Total	61,038	125,873
Accepted cases		
Reports by health professionals	8,446	11,610
Patients/consumers	9,140	27,428
Pharmaceutical companies	14,055	15,950
Other source[b]	27,076	66,096
Total	58,717	121,084
Rejected/withdrawn cases	2,321	4,789

[a] Data is subject to change due to receipt of further information related to individual reports or further case processing. Notifications for 2020-21 have been updated since the last Regulator Performance Report to reflect the most recent data.

[b] 'Other source' includes reports received from state and territory health departments (accounting for >99% of these reports) as well as reports received from other organisations that are not pharmaceutical companies.

8. Medical Devices

The Medical Devices Regulatory Framework spans the life cycle for these products, including:

- **Priority review of medical devices**: This pathway allows faster processing of applications for devices that meet certain criteria such as being a novel device or delivering significant health benefits above those devices already on the market.
- **Medical device manufacturing:** The TGA assesses the quality management systems of medical device manufacturers seeking TGA conformity assessment certification. This may be through onsite inspections or desktop assessment of third-party inspection reports, or a combination of these methods. Surveillance inspections are also undertaken to assess continuing compliance. In addition, the TGA is a Regulatory Authority of the Medical Devices Single Audit Program (MDSAP) that assesses and recognises third party Auditing Organisations for the purposes of certifying medical device manufacturers.
- **Conformity assessment:** This is the systematic examination by the manufacturer to determine that a medical device is safe and performs as intended and therefore, conforms to the Essential Principles. Certification of the manufacturer's conformity assessment procedure may (or for particular products, must) be undertaken by the TGA, or we may recognise conformity assessment certification from comparable regulators in other jurisdictions such as European notified bodies.
- **Inclusion on the ARTG:** Medical devices cannot be imported, supplied in, or exported from Australia unless they are included on the ARTG or a valid exemption applies, for example custom made medical devices, importation of samples, etc. A sponsor can apply to include a medical device on the ARTG if the device complies with the Essential Principles and appropriate conformity assessment procedures have been applied to the device.
- **Post-market monitoring:** Once a medical device has been included on the ARTG the device must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.

8.1.Conformity assessment

8.1.1 Applications

Table 39 Number of conformity assessment applications (medical devices including IVDs)

	2020-21	2021-22
	July to June	
Conformity assessment applications		
Applications received	328	191
Applications on hand	256	169
Applications completed (including withdrawn or lapsed applications).	294	278

8.1.2 Outcomes

Table 40 Outcomes of conformity assessment applications

	2020-21	2021-22
	July to June	
New		
Approved	38	51
Rejected	0	0
Withdrawn/ Lapsed	39	36
Variation (changes and re-certifications)		
Approved	192	162
Rejected	0	0
Withdrawn/ Lapsed	25	29

8.1.3 Processing timeframes

We are required to complete our review of conformity assessment applications within 255 working days.

Table 41 TGA processing times for new devices and variations

	2020-21	2021-22
	July to June	
New devices		
Mean TGA processing time (days) [a]	157	139
Median TGA processing time (days) [a]	200	168
% of applications completed within legislated timeframe (255 working days)	100%	100%
Variations (changes and recertifications)		
Mean TGA processing time (days)	124	146
Median TGA processing time (days)	117	168
% of applications completed within legislated timeframe (255 working days)	100%	100%

[a] Note that 26 applications were withdrawn prior to six TGA days processing time

8.2. Inclusion of medical devices (including IVDs)

8.2.1 Applications

Table 42 Applications for inclusion – medical devices (including IVDs)

	2020-21	2021-22
	July to June	
Class I medical devices		
Applications received	3,632	2,365
Applications completed	3,436	2,259
Applications on hand	251	321
Class I measuring medical devices		
Applications received	73	48
Applications completed	73	49
Applications on hand	3	1
Class I sterile medical devices		
Applications received	318	279
Applications completed	308	298
Applications on hand	19	16
Class IIa medical devices		
Applications received	1,579	1,377
Applications completed	1,544	1,451
Applications on hand	105	79
Class IIb medical devices		
Applications received	646	610
Applications completed	655	644
Applications on hand	88	100
Class III medical devices		
Applications received	501	469
Applications completed	365	463
Applications on hand	311	297
Active Implantable Medical Devices (AIMD)		
Applications received	20	21
Applications completed	53	19
Applications on hand	9	23
Class 1 IVDs [a]		
Applications received	125	151
Applications completed	125	141
Applications on hand	7	17
Class 2 IVDs		
Applications received	60	59
Applications completed	61	60
Applications on hand	10	9
Class 3 IVDs		
Applications received	140	526
Applications completed	142	275
Applications on hand	43	294
Class 4 IVDs		
Applications received	12	12
Applications completed	12	5
Applications on hand	0	7

[a] The number of applications for Class 1 IVD includes auto-included devices and applications completed with or without audit.

Table 43 Applications for device change requests and variations to the ARTG – medical devices (including IVDs)

	2020-21	2021-22
	July to June	
Device Change Request (DCR)		
Applications received	959	1,035
Applications completed	952	951
Applications on hand	132	310
Variations to Class III medical devices		
Applications received	97	117
Applications completed	88	123
Applications on hand	18	8
Variations to Active Implantable Medical Devices (AIMD)		
Applications received	3	0
Applications completed	2	1
Applications on hand	1	0
IVD Device Change Request (DCR)		
Applications received	71	83
Applications completed	58	72
Applications on hand	24	35
IVD Variations		
Applications received	109	97
Applications completed	85	100
Applications on hand	36	33

8.2.2 Processing times

A Level 1 audit may include clarification of the device classification, a conformity assessment procedure, and/or a review of packaging and labelling to ensure it meets requirements.

A Level 2 audit requires the information for a Level 1 audit plus one or more of the following: clinical evidence, risk management report(s), efficacy, and performance data, and/or audit reports from Notified Bodies. The target timeframe for Level 1 application audits is 30 TGA workdays and for Level 2 application audits is 60 TGA workdays (reflected in 'TGA days').

Table 44 Processing times for medical device application audits (including IVDs)

	2020-21			2021-22		
	Total completed	Processing times (TGA days)		Total completed	Processing times (TGA days)	
		Mean	Median		Mean	Median
Medical devices						
Class I applications completed without audit	3,109	1	1	1,533	2	1
Class I applications completed with audit	440	3	1	763	39	15
Non class I applications completed without audit	2,324	9	8	2,101	10	9
Non-compulsory audits (Non class I)	100	95	49	106	90	44
Level 1 compulsory audits	30	49	62	41	27	14
Level 2 compulsory audits	266	153	136	269	190	165
IVDs						
Class I IVD applications completed without audit	91	1	1	82	2	1
Class I IVD applications completed with audit	17	37	28	37	26	10
Non class I IVD applications completed without audit	57	3	2	72	2	1
IVD non-compulsory audit	6	36	20	3	23	22
IVD compulsory audit	128	61	46	219	48	35
IVD Device Change Request	58	48	51	72	67	67
IVD Variation	85	37	32	100	67	67

Table 45 Number of priority review determinations [a] granted

	2020-21	2021-22
	July-June	
Application type		
A: Conformity Assessment (priority applicant) determinations [b]	2	0
B: Medical Devices (priority applicant) determinations [b]	0	0

[a] Priority designation is a formal decision by the TGA to assign priority to the assessment of an application to include a medical device in the ARTG. Granting of priority designation does not guarantee approval for the application itself.

[b] No determinations were granted in 2021-22.

Table 46 Number of medical devices approved through the priority review pathway

	2021-22	
	July-June	
Application Type	Number of applications with Priority determinations Approved (% of Total)	Median approval time (TGA working days)
A: Conformity Assessment	0	N/A
B: Medical Devices (ARTG inclusion)	0	N/A
Total [a]	0	N/A

[a] No applications were approved in this reporting period

8.3. Post-market monitoring

8.3.1 Compliance reviews

In previous years, Class I medical devices were included in the ARTG following an online self-certification by the sponsor through a computer-generated decision process. The TGA would undertake, when necessary, a post-market compliance review for these devices. The targeted review process included surveillance of all new Class I inclusions for potentially inappropriately included Class I devices, identified by the intended purpose having certain words indicative of risk, or known issues relating to the device. The inclusion process changed from October 2020, with all new Class I medical device, Class 1 IVD medical devices, and export only ARTG applications now reviewed prior to inclusion. Requests for information are sent out where there may be uncertainty regarding the appropriateness of the classification of the device for inclusion in the ARTG.

We also conduct targeted compliance reviews initiated on a case-by-case basis. These may be conducted for devices of any Class.

8.3.2 Post-market reviews

Post-market reviews ensure that medical devices continue to comply with the applicable regulatory requirements and that the safety and performance of the medical devices (including IVDs) are maintained. The TGA uses information from both internal (for example, increase trend in adverse events) and external sources (for example, reports of new hazards) to select medical devices for post-market review.

Table 47 Medical device targeted reviews

	2020-21	2021-22
	July to June	
Post market reviews		
Reviews commenced – number of ARTG entries	1,658	5,049
Reviews completed – number of ARTG entries	851	2,554
Reviews on hand – number of ARTG entries	3,246	5,741

8.3.3 Medical device incident reports

A medical device incident is an event associated with the use or misuse of a medical device that resulted in or could have resulted in (near-incident): serious injury, illness or death to a patient, healthcare worker or other person. Australian sponsors of medical devices must actively monitor their devices' post market performance and report incidents to the TGA. Reporting of incidents, or near-incidents, by users is voluntary.

The target timeframe for processing medical device incident reports is 90 working days.

Table 48 Number of medical device incident reports and processing times

	2020-21	2021-22
	July to June	
Incident report outcomes		
Device incident reports [a]		
Reports received	6,142	8,737
Reports completed	6,010	7,978
Reports still in progress	183	207
Processing time		
Mean TGA processing time (days)	13	23.2
Median TGA processing time (days)	4	6
Percentage processed within target timeframe	97%	94%

[a] Each year begins with a number of reports on hand, additional reports are received throughout the financial year and close out some of the reports on hand.

Table 49 Medical device incident report outcomes [a]

	2020-21	2021-22
	July to June	
Incident report outcome		
Reviewed and used for trend analysis purposes	5,201	7,337
Reviewed, no further action required	518	426
Product recall	17	66
Product device correction	46	90
Hazard alert	5	32
Product notification	1	12
Safety alert	4	10
Product enhancement/improvement notice	1	2
Instructions for use amended	7	10
Referral for post-market review	59	39
Refer to another TGA Branch or Section	20	26
Company warned	5	0
Product suspended from ARTG	11	1
Product cancelled from ARTG	19	14
Manufacturing process improvements	7	8
Quality system process improvements	5	2
Maintenance carried out by the hospital	0	4
Change to design	8	6
Not device related	9	2
TGA Publication	0	20
User education	0	6
Other	151	29

[a] Outcomes are not mutually exclusive.

8.3.4 Devices manufacturing

Table 50 Outcomes of Quality Management System (QMS) audits of Australian manufacturers

Note: Due to travel restrictions related to COVID-19, the onsite/remote/hybrid inspection process continued for domestic inspections and remote auditing was implemented for overseas inspections.

	2020-21	2021-22
	July to June	
QMS audits (Australia)		
Number of audits completed	16	24
Satisfactory compliance (of completed audits)	13 (81%)	19 (80%)
Marginal compliance (of completed audits)	3 (19%)	4 (16%)
Unacceptable compliance (of completed audits)	0 (0%)	1 (4%)
Number of incomplete audits [a]	12	6
Processing time		
Initial audits conducted within 3 months of application	44%	33%
Re-audits conducted within 6 months of due date	21%	0%

[a] Where the audit has been performed however the audit report or close out is not complete

Table 51 Outcomes of QMS audits of overseas manufacturers

	2020-21	2021-22
	July to June	
QMS audits (overseas)		
Number of desktop audits conducted	31	54
Number of onsite/remote audits conducted [a]	2	7
Satisfactory compliance (of completed onsite/remote audits)	0 (0%)	2 (29%)
Marginal compliance (of completed onsite/remote audits)	0 (0%)	0 (0%)
Unacceptable compliance (of completed onsite/remote audits)	0 (0%)	1 (14%)
Incomplete audits [b]	2 (100%)	4 (57%)
Processing time		
Initial certification audits conducted within 6 months of application	50%	67%
Certification re-audits conducted within 6 months of due date	0%	0%

[a] Remote audits conducted late in the financial year

[b] Where the audit has been performed however the audit report or close out is not complete. Overseas audits resumed in May 2022 following travel restrictions.

Table 52 Outcomes of MDSAP

	2020-21	2021-22
	July to June	
MDSAP Assessments (overseas)		
Number of auditing organisation assessments	9	9
Number of witnessed manufacturing audits	5	3

9. Disinfectants

Following regulatory amendments in 2018, disinfectants that includes claims (including virucidal claims) have been downregulated from registered products to listed products. Products that make 'specific' claims to kill micro-organisms such as viruses, spores, tuberculosis bacteria and fungi are required to be included on the ARTG as a listed other therapeutic good (OTG) before they are supplied to the market.

9.1. Disinfectants

9.1.1 Applications

Table 53 Applications for listing – listed OTG

	2021-22
	July to June
Listed OTG (Disinfectants)	
Applications received [a]	120
Applications completed [b]	125
Applications on hand [c]	21

[a] Figures refer to applications received within the 2021-22 financial year
[b] Figures refer to completed applications with an outcome made in the 2021-22 financial year
[c] Figures refer to in-progress applications which were received in the 2021-22 financial year

Table 54 Outcomes of listed OTG applications

	2021-22			
	July to June			
	Number (% of Total)			
	Approved/ Accepted	Rejected/ Lapsed	Withdrawn	Total of applications
Listed OTG (Disinfectants) [a]	71 (57%)	4 (3.2%)	50 (40%)	125 (100%)

[a] Figures refer to completed applications with an outcome made in the 2021-22 financial year

10. Exports

10.1. Export only products

Table 55 Number of approved applications for export-only medicines and export certifications and relevant processing time for July 2021 to June 2022

	2020-21	2021-22	Target processing time (days)	2020-21	2021-22
	Total approved			Average processing time (days)	
Export-only medicines					
New applications	255	286	30	27	27
Variation and grouping applications	132	147	30	25	21
Export certification					
Medicines	1,540	1,622	15	13	10
Medical devices	796	1,072	10	8	6

11. Access to Unapproved Therapeutic Goods

11.1. Special Access Scheme

The Special Access Scheme (SAS) refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case-by-case basis. For this reporting period, 3 pathways existed under the scheme, and they are categorised as follows:

- Category A is a **notification pathway** which can only be accessed by medical practitioners for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.
- Category B is an **application pathway** which can be accessed by health practitioners for patients who do not fit the Category A definition. An approval letter from the TGA is required before the goods may be accessed.
- Category C is a **notification pathway** which allows health practitioners to supply goods that are deemed to have an established history of use without first seeking prior approval. The goods deemed to have an established history of use are specified in a list along with their indications and the type of health practitioner authorised to supply these products.

Any unapproved therapeutic good can potentially be supplied via the SAS although for drugs in Schedule 9 of the Poisons Standard and forbidden from supply in most states and territories.

Table 56 SAS medicine notifications and applications

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	39,675 (24%)	25,305 (15%)
Category B applications		
Approved	102,877 (97%)	121,938 (98%)
Cancelled	28 (<1%)	78 (<1%)
Withdrawn	742 (1%)	665 (<1 %)
Rejected	7 (<1%)	0 (0%)
Pending at end of reporting period	2,486 (2%)	1,411 (1%)
Total Category B applications	106,140 (65%)	124,092 (74%)
Category C notifications		
Total Category C notifications	16,814 (11%)	19,399 (12%)
Total SAS notifications/applications received (all categories)	162,629 (100%)	168,796 (100%)

Table 57 SAS medical device notifications and applications

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	5,641 (46%)	3,662 (43%)
Category B applications		
Approved	5,398 (95%)	3,559 (93%)
Cancelled	9 (<1%)	23 (<1%)
Withdrawn	86 (2%)	64 (2%)
Rejected	16 (<1%)	3 (<1%)
Pending at end of reporting period	151 (3%)	196 (5%)
Total Category B applications	5,660 (46%)	3,845 (45%)
Category C notifications		
Total Category C notifications	1,002 (8%)	1,107 (13%)
Total SAS notifications/applications received (all categories)	12,303 (100%)	8,614 (100%)

Table 58 SAS biological notifications and applications

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	78 (7%)	74 (7%)
Category B applications		
Approved	399 (80%)	239 (73%)
Cancelled	5 (1%)	14 (4%)
Withdrawn	42 (8%)	64 (20%)
Rejected	1 (<1%)	0 (0%)
Pending at end of reporting period	54 (11%)	9 (3%)
Total Category B applications	501 (47%)	326 (31%)
Category C notifications		
Total Category C notifications	485 (46%)	663 (62%)
Total SAS notifications/applications received (all categories)	1,064 (100%)	1,063 (100%)

11.2. Clinical trials

The Clinical Trial Notifications scheme provides an avenue through which unapproved therapeutic goods may be supplied for use solely for clinical trials. Unapproved therapeutic goods can include biologicals, devices or medicines or a combination of any of the 3 types of goods.

Table 59 Number of notifications for new clinical trials involving unapproved therapeutic goods received by therapeutic good type

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Therapeutic good type		
Medicine	495 (43%)	483 (41%)
Device [a]	171 (15%)	166 (14%)
Biological	7 (1%)	10 (1%)
Medicine and device	451 (40%)	514 (43%)
Device and biological	1 (<1%)	4 (<1%)
Medicine and biological	2 (<1%)	4 (<1%)
Medicine, device and biological	4 (<1%)	4 (<1%)
Total	1,131 (100%)	1,185(100%)

[a] 'Device' includes both medical device and therapeutic device categories.

Table 60 Number of new clinical trial notifications involving unapproved therapeutic goods received by phase

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Clinical trial type		
Phase 1	341 (30%)	377 (32%)
Phase 2	291 (26%)	303 (26%)
Phase 3	270 (24%)	273 (23%)
Phase 4	49 (4%)	53 (4%)
Device	175 (16%)	172 (14%)
Bioavailability/equivalence	5 (<1%)	7 (1%)
Total	1,131 (100%)	1,185 (100%)

Table 61 Number of notifications for new clinical trials and variations to previously notified clinical trials, including non-fee attracting variations, involving unapproved therapeutic goods received by therapeutic good type

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Therapeutic good type		
Medicine	1,242 (37%)	1,278 (32%)
Device [a]	301 (9%)	320 (8%)
Biological	12 (<1%)	16 (<1%)
Medicine and device	1,741 (53%)	2,344 (59%)
Device and biological	8 (<1%)	10 (<1%)
Medicine and biological	4 (<1%)	7 (<1%)
Medicine, device and biological	10 (<1%)	24 (<1%)
Total	3,318 (100%)	3,999 (100%)

[a] Device includes both medical device and therapeutic device categories. Therapeutic device means therapeutic goods (other than biologicals) consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means.

A variation to a previously notified clinical trial may include an addition of a site(s), change to a therapeutic good, or change in principal investigator etc.

Table 62 Number of new clinical trials and variations [a] to previously notified clinical trials involving unapproved therapeutic goods received by phase

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Phases		
Phase 1	933 (28%)	1,200 (30%)
Phase 2	882 (27%)	1,024 (26%)
Phase 3	1,080 (33%)	1,311 (33%)
Phase 4	104 (3%)	117 (3%)
Device	306 (9%)	338 (8%)
Bioavailability/equivalence	13 (<1%)	9 (<1%)
Total	3,318 (100%)	3,999 (100%)

[a] A variation may include any change to a previously notified clinical trial such as an additional site, change to a therapeutic good, or change in principal investigator.

11.3. Authorised Prescribers

The Authorised Prescriber Scheme allows approved medical practitioners authority to prescribe a specified unapproved therapeutic good(s) to patients who are identified by their medical condition.

Table 63 Authorised Prescriber approvals for medicines, medical devices and biologicals

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Approvals by therapeutic good type		
Number of approvals for medicines	5,087 (94%)	11,895 (98%)
Number of approvals for medical devices	311 (6%)	277 (2%)
Number of approvals for biologicals	0 (0%)	0 (0%)
Total	5,398 (100%)	12,172 (100%)

11.4. Section 19A approvals

Section 19A of the *Therapeutic Goods Act 1989* provides the legislative basis for the Secretary of the Department of Health to approve the import or supply of an overseas registered medicine that is not included in the ARTG, to mitigate a shortage of a medicine.

Table 64 Section 19A applications

	2020-21	2021-22
	July to June	
Applications processed		
New	66	89
Renewals	61	52
Total	127	141

12. Medicines and Biologicals Manufacturing

12.1. Manufacturing licences issued to Australian manufacturers

Table 65 Status of manufacturing licence applications

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Licence status (Australia) [a]		
New licences granted	13 (14%)	14 (16%)
Withdrawn application	60 (65%)	57 (67%)
Revoked licences – at request of licence holder	15 (17%)	10 (12%)
Revoked licences – TGA	0 (0%)	0 (0%)
Suspended – at request of licence holder	4 (4%)	4 (5%)
Suspended – TGA	0 (0%)	0 (0%)
Total	92 (100%)	85 (100%)

[a] As at 30 June 2022, there were 265 Australian companies holding manufacturing licences covering 410 sites.

Table 66 Outcomes of inspections of Australian manufacturers

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Compliance status (Australia)		
Number of inspections conducted	210	139
Satisfactory compliance (of completed inspections)	139 (66%)	99 (71%)
Marginal compliance (of completed inspections)	35 (17%)	25 (18%)
Unacceptable (of completed inspections)	9 (4%)	7 (5%)
Compliance under assessment	27 (13%)	8 (5%)
Processing time		
Initial inspections conducted within 3 months of application	8 of 12 (67%) [a]	9 of 15 (60%) [c]
Re-inspections conducted within 6 months of due date	117 of 162 (72%) [b]	34 of 95 (36%) [d]

[a] 4 domestic initial inspections did not achieve the three-month processing timeframe in 2020-21.
[b] 45 domestic re-inspections did not achieve the six-month processing timeframe. 18 pf the 45 delayed re-inspections were blood and biological manufacturers
[c] 6 domestic initial inspections did not achieve the three-month processing timeframe in 2021-22 due to the manufacturer not being ready for inspection.
[d] 61 domestic re-inspections did not achieve the six-month processing timeframe due to competing priorities with overseas inspections. 26 of the delayed re-inspections were blood and biological manufacturers.

12.2. Approval (certification) of overseas manufacturers

Table 67 Manufacturing certification application by status (overseas)

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Applications (overseas) [a]		
New applications received [b]	38 (36%)	71 (61%)
Re-inspection applications [b]	67 (64%)	46 (39%)
Total applications	105 (100%)	117 (100%)
Applications completed		
Certified	38 (26%)	71 (60%)
Rejected [c]	111 (74%)	48 (40%)
Total completed	149 (100%)	119 (100%)

[a] As at 30 June 2022, there were 132 overseas manufacturers covering 150 manufacturing sites that are subject to TGA inspection.
[b] Refers to applications that generated an inspection, undertaken by the TGA.
[c] Rejections include withdrawn applications.

Table 68 Outcomes of inspections of overseas manufacturers

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Inspection status (overseas)		
Number of inspections conducted	54	104
Satisfactory compliance (of completed inspections)	41 (76%)	80 (77%)
Marginal compliance (of completed inspections)	4 (7%)	17 (16%)
Unacceptable (of completed inspections)	1 (2%)	2 (2%)
Compliance under assessment at period end	8 (15%)	5 (0%)
Processing time		
Initial certification inspections conducted within 6 months of application [a c]	0 of 15 (0%)	8 of 37 (22%)
Certification re-inspections conducted within 6 months of due date [b d]	6 of 29 (21%)	2 of 66 (3%)

[a] 15 overseas initial inspections did not achieve the six-month processing timeframe.
[b] 23 overseas re-inspections did not achieve the six-month processing timeframe.
[c] 29 overseas initial inspections did not achieve the six-month processing timeframe due to the manufacturer not being ready for the inspection.
[d] 64 overseas re-inspections did not achieve the six-month processing timeframe due to competing priorities with other inspections due at the same time.

12.3. Good Manufacturing Practice (GMP) clearances

GMP clearance is required by an Australian sponsor when a step in the manufacture of a medicine or an Active Pharmaceutical Ingredient is manufactured overseas, and the manufacturing step is recorded on the ARTG.

Table 69 GMP clearance application status

	2020-21	2021-22
	July to June	
	Number (% of Total completed)	
Applications received	7,604	9,007
Applications completed		
Approved	6,778 (93%)	8,103 (91%)
Rejected	524 (7%)	799 (9%)
Total completed	7,302 (100%)	8,902 (100%)

Table 70 Number of GMP clearance applications received and completed by type from 1 July 2021 to 30 June 2022

Application Category	Applications received	Applications completed
Cancel	6	6
Extend	3,422	3,444
New	1,653	1,710
Reactivate	52	51
Variation	3,874	3,691

Table 71 Number of GMP clearance applications actioned by pathway from 1 July 2021 to 30 June 2022

Pathway	Applications received	Applications completed	Applications Approved	Applications not approved
Compliance Verification	158	1,379	1,315	64
Mutual Recognition Agreement	3,151	3,165	3,027	138

13. Recalls

13.1. Medicine recalls

Table 72 Medicine recalls by reason for recall

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Reason for recall		
Adverse reactions	12 (13%)	2 (2%)
Foreign matter	1 (1%)	4 (5%)
Illegal supply	3 (3%)	1 (1%)
Impurity	2 (2%)	10 (13%)
Labelling or Instructions	34 (35%)	24 (31%)
Mechanical or Physical defect	5 (5%)	4 (5%)
Microbial/Fungal contamination	1 (1%)	6 (8%)
Observed difference	3 (3%)	2 (2%)
Packaging or closure defect	11 (12%)	10 (13%)
Potency	5 (5%)	3 (4%)
Sterility	5 (5%)	3 (4%)
Variable content	5 (5%)	3 (4%)
Other [a]	9 (10%)	6 (8%)
Total	96 (100%)	78 (100%)

[a] 'Other' includes bioavailability, diagnostic inaccuracy, disintegration or dissolution, GMP non-compliance, therapeutic inefficiency, viral/prion contamination, wrong product, and unknown.

13.2. Medical device recalls

Table 73 Medical device (including IVDs) recalls by reason for recall

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Reason for recall		
Adverse incidents	1 (<1%)	2 (<1%)
Diagnostic inaccuracy	40 (6%)	25 (4%)
Electrical defect	34 (5%)	13 (2%)
Illegal supply	2 (<1%)	0 (0%)
Labelling and packaging	132 (20%)	115 (17%)
Mechanical and physical defects	226 (34%)	285 (43%)
Software defects	166 (25%)	170 (26%)
Sterility	25 (4%)	11 (2%)
Other [a]	39 (6%)	43 (6%)
Total	665 (100%)	664 (100%)

[a.] 'Other' includes bioavailability, disintegration/dissolution, microbial contamination, variable content, foreign matter, impurity, wrong product, therapeutic inefficiency and observed differences.

13.3. Blood and Biological recalls

Table 74 Blood recalls

	2020-21	2021-22
	July to June	
Recalls to hospital level	101	71

Table 75 Biological recalls

	2020-21	2021-22
	July to June	
Recalls to hospital level	18	6

14. Laboratory Testing

Our laboratories conduct post-market monitoring and compliance testing, investigations, and reviews, as well as market authorisation assessment of therapeutic goods.

A risk management approach, consistent with *ISO 31000: Risk Management principals and guidelines,* is used to identify products with a higher risk of not complying with the required quality standards. This risk-based, targeted approach to testing is reflected in the failure rates reported in the table below.

Laboratory testing results are made available through the *Database of TGA Laboratory Testing Results*. In addition to the routine publication of testing outcomes, we are increasingly publishing more detailed reports related to specific testing projects undertaken within our testing program.

A significant rise in the number of Medical Devices tested was observed during the reporting period. This was predominantly due to the testing of face masks and respirators included on the ARTG. Further information regarding this testing can be found on the testing of face masks and respirators webpage.

An increase in the failure rate of Complementary Medicines was also observed in this period when compared to 2020-21, however this result is affected by the lower number of samples tested over the reporting period due to the pandemic. Similarly, an increase in the failure rate of Pacific Medicines Testing Program samples was observed in 2021-22 as compared to 2020-21, and this is most likely due to the specific targeting of testing, as well as the inclusion of testing of face masks.

The significant increase in workloads due to the COVID-19 pandemic have affected compliance with usual timeframe targets.

Table 76 Samples and products tested by type of therapeutic good and percentage which failed

		2020-21	2021-22
		July to June	
Therapeutic good type			
Prescription medicines	Total	869	900
	% fail	2%	2%
OTC medicines	Total	81	0
	% fail	6%	0%
Complementary medicines [a]	Total	18	53
	% fail	39%	9%
Medical devices	Total	827	1,738
	% fail	52%	35%
External [a]	Total	22	8
	% fail	9%	13%
Pacific Medicines Testing Program	Total	53	26
	% Fail	43%	9%
Unregistered [b]	Total	230	371
	% fail	32%	73%
Total samples (excluding AHQ samples)		2,100	3,096
Total samples [c]		2,684	3,449
Percentage fail		27%	30%
Total number of products tested [d]		1,003	1,345

[a] Performed on request for overseas regulators, and encompasses medicines and medical devices.

[b] 'Unregistered' refers to products that meet the definition of therapeutic goods but are not included on the ARTG or otherwise specifically exempted from this requirement in the legislation. This often includes adulterated complementary medicines or counterfeit products.

[c] Includes accreditation, harmonisation and quality control (AHQ) samples.

[d] We may test a number of samples of each product per reporting period.

Table 77 Samples that failed laboratory testing by reason for July 2021 to June 2022

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Complementary medicines	External	Pacific Medicines Testing Program	Total (% fail)
Contamination	2	0	0	211	1	0	1	215 (7%)
Formulation	0	0	2	33	4	1	6	46 (1%)
Label and packaging deficiencies	109	0	0	0	0	0	0	109 (4%)
Performance [a]	504	0	0	0	0	0	2	506 (16%)
Physical or mechanical properties	1	0	15	0	0	0	0	16 (<1%)
Unregistered	0	0	0	27	0	0	0	27 (<1%)
Total	616	0	17	271	5	1	9	919 (100%)

[a] Performance means failure of the product to meet criteria/requirements critical to the intended purpose of the goods.

Table 78 Batch release and export certification

	2020-21	2021-22
	July to June	
Batch releases and certifications		
Batch release [a]	656	588
Export certification [b]	18	18

[a] Evaluation of batch release documentation for vaccines, biotechnology and blood products.
[b] Certification of biological products being exported from Australian manufacturers to overseas markets.

The TGA provides the World Health Organisation-approved certificates for batches of biological products to be exported by Australian manufacturers to overseas markets.

Table 79 Target timeframes in working days for laboratory testing by priority and testing type

Priority of testing	Biochemical/ chemical testing	Microbiological testing	Medical device testing
Urgent [a]	20 (95% of target times to be met)	40 (95% of target times to be met)	20 (95% of target times to be met)
Priority	40 (80% of target times to be met)	50 (80% of target times to be met)	40 (80% of target times to be met)
Routine	50	50	50

[a] Testing on products linked to potential public safety concerns are assigned to the 'Urgent' testing category. Urgent testing may impact on the timeframes for priority and routine testing. Priority is given to testing of products with the highest risk of a quality deficiency.

Table 80 Compliance with testing timeframes [a] for July 2021 to June 2022

	Priority	Number (% of Total)
Therapeutic good type [b]		
Medical devices	Routine	1,733 (57%)
	Priority	5 (80%)
	Urgent	0 (0%)
OTC medicines	Routine	0 (0%)
	Priority	0 (0%)
	Urgent	0 (0%)
Prescription medicines	Routine	23 (87%)
	Priority	4 (25%)
	Urgent	0 (0%)
Complementary Medicines	Routine	16 (75%)
	Priority	37 (46%)
	Urgent	0 (0%)
Unregistered products	Routine	80 (65%)
	Priority	281 (77%)
	Urgent	10 (20%)

[a] Samples involving complex biological assays are excluded from the target turnaround timeframes.
[b] Low numbers of samples within categories may affect compliance percentages.

Table 81 Face Mask Testing and percentage which were non-compliant by reason

The Laboratories received 1,552 samples of face masks for testing. Of these, 52 were from the National Medical Stockpile and 42 were from State/Territory Health Departments.

Testing for face masks varies based on the product type and claims and can include assessments for Design & Quality, Fluid Resistance, Particulate Filtration Efficiency, and Sterility.

	Tested	% Non-compliant
Design and Quality	1,407	13%
Fluid Resistance	1,130	35%
Particulate Filtration Efficiency	374	26%
Sterility	20	15%

15. Regulatory Compliance

The TGA conducts compliance and enforcement activities against a risk-based compliance framework. A range of tools are utilised to encourage compliance and address non-compliance including education and guidance, warnings, the issue of infringements, and/or product suspensions or cancellations. Investigations may also result in criminal or civil court proceedings. For advertising related compliance and enforcement outcomes and activities, please refer to the 2021-22 Advertising Compliance Annual Report.

Table 82 Number of compliance actions taken against completed investigations

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Completed investigations		
No offence identified	508 (12%)	357 (4%)
Goods released under Personal Import Scheme	290 (7%)	285 (3%)
Referred internally	22 (<1%)	27 (<1%)
Referred to external agency	95 (2%)	227 (3%)
Warning letters issued [a]	3,072 (75%)	8,015 (89%)
Infringement notices [b]	89 (2%)	74 (<1%)
Referred to the Commonwealth Director of Public Prosecutions	2 (<1%)	1 (<1%)
Criminal prosecution	2 (<1%)	2 (<1%)
Total [c]	4,088 (100%)	8,988 (100%)
Units of goods referred to ABF for destruction [d]	1,197,300	5,137,491

[a] The category 'warning letters issued' can include goods destroyed as prohibited imports and goods re-exported.
[b] For infringement notices issued for advertising contraventions please refer to the Therapeutic Goods Advertising Compliance Annual Report 2021-22.
[c] There can be multiple actions per case resulting in a higher total figure than shown in finalised cases below.
[d] Units refers to single dosage unit e.g. 1 tablet, 1 capsule, 1 tub of powder or a single device.

Table 83 Regulatory compliance investigations by number

	2020-21	2021-22
	July to June	
Compliance cases [a]		
Cases received	4,215	11,501
Cases active [b]	919	2,213
Cases finalised [b]	4,049	8,625

[a] These figures are based on case numbers and not actions taken or offence types.
[b] Cases may not have been received in the same financial year.

Table 84 Number of different products investigated

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Therapeutic good type		
Prescription medicines (Schedule 4 and Schedule 8)	4,795 (73%)	19,296 (84%)
Schedule 9 medicines	12 (<1%)	5 (<1%)
Schedule 10 medicines	47 (<1%)	17 (<1%)
Medical devices	421 (6%)	442 (2%)
Complementary and homoeopathic medicines	430 (7%)	196 (<1%)
OTC medicines	58 (<1%)	42 (<1%)
Biological and blood products	3 (<1%)	3 (<1%)
Other [a]	846 (13%)	3,076 (13%)
Total [b]	6,612 (100%)	23,077 (100%)

[a] Due to system technical issues, some investigations were unable to be categorised by therapeutic good type.
[b] Multiple therapeutic goods types may appear in a single case.

Table 85 Regulatory compliance investigations by special interest categories

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Compliance investigation category		
Unregistered	9,582 (98%)	21,847 (95%)
Registered	186 (2%)	151 (<1%)
Counterfeit product	22 (<1%)	1,079 (5%)
Total [a]	9,790 (100%)	23,077 (100%)

[a] There can be multiple special interest categories in a single case.

Table 86 Number of offence types related to completed cases

	2020-21	2021-22
	July to June	
	Number (% of total)	
Offence type		
Import	4,278 (97%)	9,237 (97%)
Export	11 (<1%)	3 (<1%)
Manufacture	4 (<%)	4 (<1%)
Supply	137 (3%)	261 (3%)
Advertising	0 (0%)	4 (<1%)
Total completed [a]	4,430 (100%)	9,509 (100%)

[a] There can be multiple offences in a single case.

16. Pharmacovigilance Inspection Program

Table 87 Pharmacovigilance Inspection Program inspections undertaken and deficiencies identified

	2020-21	2021-22
	July to June	
Compliance investigation category		
Total inspections completed	6	10
Total with completed findings	6	10
Critical deficiencies [a]	3	2
Major deficiencies [b]	27	32
Minor deficiencies [c]	15	28
Average deficiencies per inspection	0.5 critical 4.5 major 2.5 minor	0.2 critical 3.2 major 2.8 minor

[a] A deficiency in pharmacovigilance systems, practices or processes that adversely affects the rights, safety, or well-being of patients or that poses a potential risk to public health or that represents a serious violation of applicable legislation and guidelines. Deficiencies classified as critical may include a pattern of deviations classified as major. A critical deficiency also occurs when a sponsor is observed to have engaged in fraud, misrepresentation, or falsification of data. Deficiencies are classified by the assessed risk level and may vary depending on the nature of medicine. In some circumstances an otherwise major deficiency may be categorised as critical.

[b] A deficiency in pharmacovigilance systems, practices or processes that could potentially adversely affect the rights, safety, or well-being of patients or that could potentially pose a risk to public health or that represents a violation of applicable legislation and guidelines. Deficiencies classified as major may include a pattern of deviations classified as minor.

[c] A deficiency in pharmacovigilance systems, practices or processes that would not be expected to adversely affect the rights, safety, or well-being of patients. A deficiency may be minor either because it is judged as minor or because there is insufficient information to classify it as major or critical.

17. Reporting of Medicine Shortages

Table 88 Number of medicine shortage reports [a] by shortage reason

	2020-21	2021-22
	July to June	
	Number (% of Total)	
Shortages Reported		
New – Commercial changes	36 (3%)	37 (3%)
New – Discontinuation	135 (11%)	177 (15%)
New – Manufacturing related	445 (36l%)	666 (56%)
New – Other [b]	416 (33%)	0 (0%)
New – Product recall	2 (<1%)	5 (<1%)
New – Unexpected increase in demand	202 (16%)	135 (11%)
New – Unexpected increase in demand due to other sponsors unable to supply	3 (<1%)	42 (4%)
New – Transport / Logistic issues / Storage capacity issues	8 (<1%)	122 (10%)
New – Seasonal depletion of stock	0 (0%)	6(<1%)
Total	1,247 (100%)	1,190 (100%)

[a] New reports only, does not include updates of previously reported shortages.
[b] 'Other' was removed as a shortage reason from 1 June 2021.

Table 89 Number of medicine shortage notifications processed

	2020-21	2021-22
	July to June	
Notifications processed		
New	1,247	1,190
Update [a]	3,978	3,386
Total	5,225	4,576

[a] Updates of previously reported shortages, including updates to 'Resolved' status. Mandatory reporting of all shortages of prescription medicines and select over-the-counter medicines commenced 1 January 2019.

FOI 26-2331- links to face mask and respirator information on current site and Trove

Pages

Current (unchanged since 8 September 2021): Face masks and COVID-19 | Therapeutic Goods Administration (TGA)

Trove: 21 Jan 2021 - Face masks and COVID-19 | Therapeutic Goods Administration (TGA) - Trove

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Coronavirus (COVID-19): Information on medicines and medical devices *(collection of COVID-19 information on previous website)*

06 Jun 2020 - www.tga.gov.au/collection/covid-19?f[0]=field_tags:9451 - Trove (filtered by Protective equipment)

22 Sep 2020 - Coronavirus (COVID-19): Information on medicines and medical devices | Therapeutic Goods Administration (TGA) - Trove (filtered by new term added - Face masks and PPE)

Current: Post-market review of COVID-19 face masks | Therapeutic Goods Administration (TGA)

Trove: 07 Jun 2020 - Post-market review of face masks: Cancelled ARTG entries | Therapeutic Goods Administration (TGA) - Trove

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Current: Post-market review and testing of disposable face masks and respirators | Therapeutic Goods Administration (TGA)

Trove: 16 Sep 2022 - Face mask and respirator test reports | Therapeutic Goods Administration (TGA) - Trove

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Current: Understanding standards for face masks and respirators | Therapeutic Goods Administration (TGA)

Trove: 16 Nov 2024 - Understanding standards for face masks and respirators | Therapeutic Goods Administration (TGA) - Trove

Trove: 22 Jan 2021 - Guidance on medical/surgical face masks and respirator standards - key performance aspects | Therapeutic Goods Administration (TGA) - Trove

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Current: Evidence requirements for face masks that are medical devices | Therapeutic Goods Administration (TGA)

Trove: 22 Jan 2021 - Evidence requirements for face masks that are medical devices | Therapeutic Goods Administration (TGA) - Trove

Current: COVID-19 Personal Protective Equipment (PPE) | Therapeutic Goods Administration (TGA)

Trove: 16 Sep 2022 - COVID-19 personal protection products | Therapeutic Goods Administration (TGA) - Trove

News articles

Current (News article from 9 December 2021): Regulation of Personal Protective Equipment and COVID-19 | Therapeutic Goods Administration (TGA)

Current: Reuse of face masks and gowns during the COVID-19 pandemic | Therapeutic Goods Administration (TGA)

Current: Reuse of face masks and gowns during the COVID-19 pandemic | Therapeutic Goods Administration (TGA)

Trove: 25 May 2020 - Reuse of face masks and gowns during the COVID-19 pandemic | Therapeutic Goods Administration (TGA) - Trove

Current (from 18 December 2020): Use of face masks during MRI examinations | Therapeutic Goods Administration (TGA)

Datasets

Current: Face mask cancellations | Therapeutic Goods Administration (TGA)

Trove: 16 Sep 2022 - Face mask cancellations | Therapeutic Goods Administration (TGA) - Trove

Current: Face mask market actions | Therapeutic Goods Administration (TGA)

Trove: 16 Sep 2022 - Face mask market actions | Therapeutic Goods Administration (TGA) - Trove

Current: Face mask non-compliance notices | Therapeutic Goods Administration (TGA)

Trove: 16 Sep 2022 - Face mask non-compliance notices | Therapeutic Goods Administration (TGA) - Trove

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

Medical device summary

You searched for the following **3 medical devices** between **01/01/2020 – 31/12/2022**:

- Med-Con Pty Ltd - Med-Con - level 3 surgical mask with ties - Mask, surgical, single use - Mask, surgical, single use
- Med-Con Pty Ltd - Med-Con-170516, Level 3 loop masks - Mask, surgical, single use - Mask, surgical, single use
- Med-Con Pty Ltd - NMS - MASK, SURGICAL, FACE, LEVEL 3, LOOPS (MEDCON) - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. < http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
- The DAEN - medical devices does not contain all known safety information about a particular medical device. Please do not make an assessment about the safety of a medical device based on the information in the DAEN - medical devices.

The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. < http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite < http://www.healthinsite.gov.au/>

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of the adverse events reported to the TGA, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose. To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Results

Number of reports: 3

Report number[i]	Report date[ii]	Trade name[iii]	Sponsor[iv]	Manufacturer[v]	ARTG number[vi]	GMDN term[vii]
65211	20/08/2020	Med-Con - level 3 surgical mask with ties - Mask, surgical, single use	Med-Con Pty Ltd	Med-Con Pty Ltd	109872	Mask, surgical, single use
65179	28/08/2020	Med-Con-170516, Level 3 loop masks - Mask, surgical, single use	Med-Con Pty Ltd	Med-Con Pty Ltd	109872	Mask, surgical, single use
65276	7/09/2020	NMS - MASK, SURGICAL, FACE, LEVEL 3, LOOPS (MEDCON) - Mask, surgical, single use	Med-Con Pty Ltd	Med-Con Pty Ltd	109872	Mask, surgical, single use

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

Australian Government
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Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Kimberly Clark Aust Pty Ltd - TECHNOL FLUIDSHIELD PFR95 N95 - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
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The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

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- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

About the release of this information

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Results

Number of reports: 1

Report number[i]	63061
Report date[ii]	8/04/2020
Trade name[iii]	TECHNOL FLUIDSHIELD PFR95 N95 - Mask, surgical, single use
Sponsor[iv]	Kimberly Clark Aust Pty Ltd
Manufacturer[v]	Kimberly Clark Aust Pty Ltd
ARTG number[vi]	128674
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Many masks kept in stock for emergency have had to be thrown out due to their elastic straps perishing. The boxes do not have any use-by date, therefore it was impossible to know how old the stock is or whether the latex/rubber.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Material Integrity Problem, Labelling, Instructions for Use or Training Problem
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Cranberry M Sdn Bhd - Cranberry Repel Face Mask Wide Angle Shield - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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The TGA medical device safety monitoring program

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Results

Number of reports: 1

Report number[i]	62177
Report date[ii]	21/02/2020
Trade name[iii]	Cranberry Repel Face Mask Wide Angle Shield - Mask, surgical, single use
Sponsor[iv]	GIENIC PTY LTD
Manufacturer[v]	Cranberry M Sdn Bhd
ARTG number[vi]	212604
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	Repel Face Mask Wide Angle Shield
Software version[xii]	-
Event description[xiii]	No expiry date.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Labelling, Instructions for Use or Training Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **3 medical devices** between **01/01/2020 – 31/12/2022**:

- 3M Healthcare - 1870+ Aura healthcare particulate respirator - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use
- 3M Healthcare - 3M Aura 1870+ N95 Mask - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use
- 3M Healthcare - 3M™ Health Care Aura Particulate Respirator 1870+ - Surgical/medical respirator - Surgical/medical respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

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- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
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The TGA medical device safety monitoring program

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- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

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Results

Number of reports: 2

Report number[i]	72853
Report date[ii]	4/01/2022
Trade name[iii]	3M™ Health Care Aura Particulate Respirator 1870+ - Surgical/medical respirator
Sponsor[iv]	3M Australia Pty Ltd
Manufacturer[v]	3M Healthcare
ARTG number[vi]	255656
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	1870+
Software version[xii]	-
Event description[xiii]	Device strap snapped during use on at least two occasions.
Reported event outcome[xiv]	No injury
Report source category[xv]	Industry
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	74528
Report date[ii]	2/09/2022
Trade name[iii]	1870+ Aura healthcare particulate respirator - Surgical/medical respirator, single-use
Sponsor[iv]	3M Australia Pty Ltd
Manufacturer[v]	3M Healthcare
ARTG number[vi]	255656
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	1870+
Software version[xii]	-
Event description[xiii]	Anaphylactic reaction during use of the Aura 1870+ respirator.
Reported event outcome[xiv]	Injury
Report source category[xv]	Industry
Event type[xvi]	Patient Device Interaction Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Mun Global Sdn Bhd - PRIMEON ARTEMIS - MASK, SURGICAL, FACE, LEVEL 2, PLEATED, EAR LOOP - Mask, surgical, single use - Mask, surgical, single use

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Results

Number of reports: 1

Report number[i]	83395
Report date[ii]	22/11/2022
Trade name[iii]	PRIMEON ARTEMIS - MASK, SURGICAL, FACE, LEVEL 2, PLEATED, EAR LOOP - Mask, surgical, single use
Sponsor[iv]	Mun Australia Pty Ltd
Manufacturer[v]	Mun Global Sdn Bhd
ARTG number[vi]	290961
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Unsuitable for coverage and seal for small or medium sized faces and material is scratchy on face.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Material Integrity Problem, Human-Device Interface Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **3 medical devices** between **01/01/2020 – 31/12/2022**:

- Xian Tao Fushi Protective Products Co Ltd - Fullstar Mask, surgical, single use - Mask, surgical, single use
- Xian Tao Fushi Protective Products Co Ltd - Fullstar Masks - Mask, surgical, single use - Mask, surgical, single use
- Xian Tao Fushi Protective Products Co Ltd - Fullstar Surgical Face Mask - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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Results

Number of reports: 3

Report number[i]	62928
Report date[ii]	6/04/2020
Trade name[iii]	Fullstar Surgical Face Mask - Mask, surgical, single use
Sponsor[iv]	Ultra Health Medical Pty Ltd
Manufacturer[v]	Xian Tao Fushi Protective Products Co Ltd
ARTG number[vi]	296802
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Multiple issues
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	63122
Report date[ii]	20/04/2020
Trade name[iii]	Fullstar Masks - Mask, surgical, single use
Sponsor[iv]	Ultra Health Medical Pty Ltd
Manufacturer[v]	Xian Tao Fushi Protective Products Co Ltd
ARTG number[vi]	296802
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Allergic reaction.
Reported event outcome[xiv]	Injury
Report source category[xv]	Other
Event type[xvi]	Patient Device Interaction Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	63370
Report date[ii]	18/05/2020
Trade name[iii]	Fullstar Mask, surgical, single use
Sponsor[iv]	Ultra Health Medical Pty Ltd
Manufacturer[v]	Xian Tao Fushi Protective Products Co Ltd
ARTG number[vi]	296802
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Medical staff and nursing staff, felt unwell, severe eye irritation, headaches.
Reported event outcome[xiv]	
Report source category[xv]	Health Professional
Event type[xvi]	Patient Device Interaction Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

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[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

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[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- BSN Medical (Aust) Pty Ltd - Proshield, N95 mask - Mask, <specify> - Mask, (specify)

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
- The DAEN - medical devices does not contain all known safety information about a particular medical device. Please do not make an assessment about the safety of a medical device based on the information in the DAEN - medical devices.

The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

About the release of this information

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Results

Number of reports: 1

Report number[i]	63819
Report date[ii]	16/06/2020
Trade name[iii]	Proshield, N95 mask - Mask, <specify>
Sponsor[iv]	BSN Medical (Aust) Pty Ltd
Manufacturer[v]	BSN Medical (Aust) Pty Ltd
ARTG number[vi]	305431
GMDN Term[vii]	Mask, (specify)
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	N95 proshield respirator
Software version[xii]	-
Event description[xiii]	strap failure and breakages N95 mask
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- O&M Halyard Inc - Halyard Fluidshield 3 Procedure Mask with Visor - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
- The DAEN - medical devices does not contain all known safety information about a particular medical device. Please do not make an assessment about the safety of a medical device based on the information in the DAEN - medical devices.

The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

About the release of this information

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Results

Number of reports: 1

Report number[i]	64397
Report date[ii]	16/07/2020
Trade name[iii]	Halyard Fluidshield 3 Procedure Mask with Visor
Sponsor[iv]	O&M Halyard Australia Pty Ltd
Manufacturer[v]	O&M Halyard Inc
ARTG number[vi]	314855
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	47147
Software version[xii]	-
Event description[xiii]	Masks were reportedly of poor quality.
Reported event outcome[xiv]	Injury
Report source category[xv]	Health Professional
Event type[xvi]	, Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Xiantao S&J Protective Products Co Ltd - SUB - MASK, SURGICAL, LEVEL 2 (SWISS MADE BRANDS) - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
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The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

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Results

Number of reports: 1

Report number[i]	65277
Report date[ii]	7/09/2020
Trade name[iii]	SUB - MASK, SURGICAL, LEVEL 2 (SWISS MADE BRANDS)
Sponsor[iv]	SWISS MADE BRANDS PTY LTD
Manufacturer[v]	Xiantao S&J Protective Products Co Ltd
ARTG number[vi]	331305
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	202003
Software version[xii]	-
Event description[xiii]	Rash after device use
Reported event outcome[xiv]	Injury
Report source category[xv]	Health Professional
Event type[xvi]	Patient Device Interaction Problem
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **3 medical devices** between **01/01/2020 – 31/12/2022**:

- Ningbo Yingmed Medical Instruments Co Ltd - Mask, surgical, single use - Mask, surgical, single use
- Ningbo Yingmed Medical Instruments Co Ltd - Strapit Respirator K95 RMSK-01 - Mask, surgical, single use - Mask, surgical, single use
- Ningbo Yingmed Medical Instruments Co Ltd - Strapit SURGIMASK - Level 2 High filtration face mask - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
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The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

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Results

Number of reports: 3

Report number[i]	63239
Report date[ii]	4/05/2020
Trade name[iii]	Strapit Respirator K95 RMSK-01 - Mask, surgical, single use
Sponsor[iv]	Strapit Medical and Sports Supplies Pty Ltd
Manufacturer[v]	Ningbo Yingmed Medical Instruments Co Ltd
ARTG number[vi]	331428
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	RMSK-01
Software version[xii]	-
Event description[xiii]	Vendor of KN95 respirator mask claimed its product had "optimal fluid resistance"
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Labelling, Instructions for Use or Training Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	63263
Report date[ii]	5/05/2020
Trade name[iii]	Mask, surgical, single use
Sponsor[iv]	Strapit Medical and Sports Supplies Pty Ltd
Manufacturer[v]	Ningbo Yingmed Medical Instruments Co Ltd
ARTG number[vi]	331428
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Surgical face mask quality issues.
Reported event outcome[xiv]	Injury
Report source category[xv]	Other
Event type[xvi]	Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Report number[i]	63530
Report date[ii]	27/05/2020
Trade name[iii]	Strapit SURGIMASK - Level 2 High filtration face mask
Sponsor[iv]	Strapit Medical and Sports Supplies Pty Ltd
Manufacturer[v]	Ningbo Yingmed Medical Instruments Co Ltd
ARTG number[vi]	331428
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	SURGMSK2
Software version[xii]	-
Event description[xiii]	Poor quality masks which don't seal over the nose, flimsy ear loop style straps, prone to breakage and cause skin irritation.
Reported event outcome[xiv]	Injury
Report source category[xv]	Other
Event type[xvi]	Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Footnotes

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[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

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[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **2 medical devices** between **01/01/2020 – 31/12/2022**:

- Alpha Pro Tech Inc - Alpha Protech Critical Cover PFL - Surgical/medical respirator, single-use - Public respirator, single-use
- Alpha Pro Tech Inc - AlphaProTech N-95 Particulate Respirator - Public respirator, single-use - Public respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

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- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

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Results

Number of reports: 2

Report number[i]	68451
Report date[ii]	2/03/2021
Trade name[iii]	AlphaProTech N-95 Particulate Respirator - Public respirator, single-use
Sponsor[iv]	Olamte Pty Ltd
Manufacturer[v]	Alpha Pro Tech Inc
ARTG number[vi]	331773
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Alpha Pro Tech N95 respirators straps are breaking mid-wear, wirings ripping through masks and hurting the wearer, tears in fabric.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Material Integrity Problem,
Other medical devices reported as being used[xvii]	None

Report number[i]	76193
Report date[ii]	14/02/2022
Trade name[iii]	Alpha Protech Critical Cover PFL - Surgical/medical respirator, single-use
Sponsor[iv]	Olamte Pty Ltd
Manufacturer[v]	Alpha Pro Tech Inc
ARTG number[vi]	331773
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	N95 Respirator
Software version[xii]	n/a
Event description[xiii]	The masks were found to be not up to standard. The were gaping at the sides so air was coming in and out. They didn't seal properly. The straps were very thin and as a result, the straps were frequently snapping.
Reported event outcome[xiv]	No injury
Report source category[xv]	Consumer
Event type[xvi]	Insufficient Information
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- BYD Precision Manufacture Co Ltd - BYD N95 Mask - Public respirator, single-use - Public respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

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- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

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The TGA medical device safety monitoring program

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Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

About the release of this information

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Results

Number of reports: 1

Report number[i]	75872
Report date[ii]	3/02/2022
Trade name[iii]	BYD N95 Mask - Public respirator, single-use
Sponsor[iv]	BYD AUSTRALIA PTY LTD
Manufacturer[v]	BYD Precision Manufacture Co Ltd
ARTG number[vi]	332300
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	N95
Software version[xii]	-
Event description[xiii]	Allergic reaction to N95 mask.
Reported event outcome[xiv]	Injury
Report source category[xv]	Consumer
Event type[xvi]	Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

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[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **2 medical devices** between **01/01/2020 – 31/12/2022**:

- Lakshan Global Solutions - Brandless Face Masks which is sold as ASTM Level 3 masks - Mask, (specify)
- Lakshan Global Solutions - Immersifai - Mask, <specify> - Mask, (specify)

Important information on the Database of Adverse Event Notifications – medical devices

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Results

Number of reports: 2

Report number[i]	63132
Report date[ii]	23/04/2020
Trade name[iii]	Brandless Face Masks which is sold as ASTM Level 3 masks
Sponsor[iv]	IMMERSIFAI PTY LTD
Manufacturer[v]	Lakshan Global Solutions
ARTG number[vi]	332828
GMDN Term[vii]	Mask, (specify)
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	Unknown
Software version[xii]	Unknown
Event description[xiii]	The sponsor advertise face mask product as ATSM 3 when only registered as a class I.
Reported event outcome[xiv]	
Report source category[xv]	Other
Event type[xvi]	Labelling, Instructions for Use or Training Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	63213
Report date[ii]	6/05/2020
Trade name[iii]	Immersifai - Mask, <specify>
Sponsor[iv]	IMMERSIFAI PTY LTD
Manufacturer[v]	Lakshan Global Solutions
ARTG number[vi]	332828
GMDN Term[vii]	Mask, (specify)
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Concerns device does not comply with TGA regulations.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Labelling, Instructions for Use or Training Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **4 medical devices** between **01/01/2020 – 31/12/2022**:

- Wuhan Topmed Trading Co - Soft Med - Surgical Mask - Mask, surgical, single use
- Wuhan Topmed Trading Co - Softmed - MASK, SURGICAL, FACE, LEVEL 3, PLEATED, EARL - Mask, surgical, single use
- Wuhan Topmed Trading Co - SoftMed - Mask, surgical, single use - Mask, surgical, single use
- Wuhan Topmed Trading Co - Softmed Face Masks - 50 pk - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

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Results

Number of reports: 4

Report number[i]	63818
Report date[ii]	16/06/2020
Trade name[iii]	Soft Med - Surgical Mask
Sponsor[iv]	M House Pty Ltd
Manufacturer[v]	Wuhan Topmed Trading Co
ARTG number[vi]	333133
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	Softmed 3 ply mask
Software version[xii]	-
Event description[xiii]	The Softmed product that was received into THS stock has been associated with increased reports of poor quality, fit and faults.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Manufacturing, Packaging or Shipping Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	64329
Report date[ii]	14/07/2020
Trade name[iii]	SoftMed - Mask, surgical, single use
Sponsor[iv]	M House Pty Ltd
Manufacturer[v]	Wuhan Topmed Trading Co
ARTG number[vi]	333133
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Elastic that holds the mask around the ears breaks away from the mask.
Reported event outcome[xiv]	No injury
Report source category[xv]	Consumer
Event type[xvi]	Mechanical Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	64581
Report date[ii]	27/07/2020
Trade name[iii]	Softmed Face Masks - 50 pk - Mask, surgical, single use
Sponsor[iv]	M House Pty Ltd
Manufacturer[v]	Wuhan Topmed Trading Co
ARTG number[vi]	333133
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Masks have all broken within a minute of wearing and have caused skin rash/irritation in this short time.
Reported event outcome[xiv]	Injury
Report source category[xv]	Consumer
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	64670
Report date[ii]	3/08/2020
Trade name[iii]	Softmed - MASK, SURGICAL, FACE, LEVEL 3, PLEATED, EARL
Sponsor[iv]	M House Pty Ltd
Manufacturer[v]	Wuhan Topmed Trading Co
ARTG number[vi]	333133
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	Softmed L3DFM-RSEA
Software version[xii]	-
Event description[xiii]	Ear loops continue to break.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

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[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **2 medical devices** between **01/01/2020 – 31/12/2022**:

- Sentry Medical Pty Ltd - MASK, SURGICAL, FACE, LEVEL 2, EARLOOP (OWEAR - Mask, surgical, single use
- Sentry Medical Pty Ltd - O Wear, Sentry Medical, Mask, Surgical, Level 2, Ear loops - Mask, surgical, single use

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Results

Number of reports: 2

Report number[i]	69188
Report date[ii]	31/03/2021
Trade name[iii]	MASK, SURGICAL, FACE, LEVEL 2, EARLOOP (OWEAR
Sponsor[iv]	Sentry Medical Pty Ltd
Manufacturer[v]	Sentry Medical Pty Ltd
ARTG number[vi]	333199
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	MSK100
Software version[xii]	-
Event description[xiii]	Earloops frequently break
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	69189
Report date[ii]	31/03/2021
Trade name[iii]	O Wear, Sentry Medical, Mask, Surgical, Level 2, Ear loops
Sponsor[iv]	Sentry Medical Pty Ltd
Manufacturer[v]	Sentry Medical Pty Ltd
ARTG number[vi]	333199
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	MSK100
Software version[xii]	-
Event description[xiii]	Loops separating from main body of mask.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Mechanical Problem
Other medical devices reported as being used[xvii]	None

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Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- ESound Medical Device Co Ltd - ESound Med - Medical protective surgical face mask - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

About the release of this information

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Results

Number of reports: 1

Report number[i]	65081
Report date[ii]	27/08/2020
Trade name[iii]	ESound Med - Medical protective surgical face mask
Sponsor[iv]	WT Health Pty Ltd
Manufacturer[v]	ESound Medical Device Co Ltd
ARTG number[vi]	333708
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	200411615
Software version[xii]	-
Event description[xiii]	Concerns of breathing the odour of masks could cause breathing issues for staff.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Chemical Problem
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Wuxi JHT Group Co Ltd - Virafree- Disposable Protective Face Mask - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
- The DAEN - medical devices does not contain all known safety information about a particular medical device. Please do not make an assessment about the safety of a medical device based on the information in the DAEN - medical devices.

The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

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Results

Number of reports: 1

Report number[i]	64719
Report date[ii]	6/08/2020
Trade name[iii]	Virafree- Disposable Protective Face Mask
Sponsor[iv]	Decor Innovations Pty Ltd
Manufacturer[v]	Wuxi JHT Group Co Ltd
ARTG number[vi]	334097
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Issues: -They use the statement “TGA Approved”. -There is no sponsor or manufacturer info on the packaging or any leaflet.
Reported event outcome[xiv]	No injury
Report source category[xv]	Industry
Event type[xvi]	Use of Device Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Nantong Senyou Carbon Fiber Co Ltd - Senyou N95 carbon fiber Face mask - Public respirator, single-use - Public respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

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Other useful sources of information on Australian medical devices

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Results

Number of reports: 1

Report number[i]	63686
Report date[ii]	27/05/2020
Trade name[iii]	Senyou N95 carbon fiber Face mask - Public respirator, single-use
Sponsor[iv]	Nottage International Pty Ltd
Manufacturer[v]	Nantong Senyou Carbon Fiber Co Ltd
ARTG number[vi]	334347
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Surgical face mask quality issues.
Reported event outcome[xiv]	
Report source category[xv]	Health Professional
Event type[xvi]	Protective Measures Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Safeway Industry Healthcare - Ultra Health Medical - Level 2 - 120mmHg disposable face mask - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
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About the Database of Adverse Event Notifications (DAEN) - medical devices

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The TGA medical device safety monitoring program

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Other useful sources of information on Australian medical devices

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Results

Number of reports: 1

Report number[i]	80641
Report date[ii]	22/07/2022
Trade name[iii]	Ultra Health Medical - Level 2 - 120mmHg disposable face mask - Mask, surgical, single use
Sponsor[iv]	Ultra Health Medical Pty Ltd
Manufacturer[v]	Safeway Industry Healthcare
ARTG number[vi]	334569
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	A worker has had an a serious skin reaction when wearing an Ultra Health Disposable face Mask.
Reported event outcome[xiv]	Injury
Report source category[xv]	Other
Event type[xvi]	Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

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[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **2 medical devices** between **01/01/2020 – 31/12/2022**:

- 3M Company 3M Healthcare dba 3M Consumer Health Care 3M Center - 1860 3M Cupped Particulate Respirator & Surgical Mask - Surgical Respirator - Public respirator, single-use
- 3M Company 3M Healthcare dba 3M Consumer Health Care 3M Center - 3M Aura N95 P2 1870+ Particulate Respirator Surgical Mask Flat Fold - Public respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

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- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
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The TGA medical device safety monitoring program

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You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

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Results

Number of reports: 2

Report number[i]	71045
Report date[ii]	5/08/2021
Trade name[iii]	1860 3M Cupped Particulate Respirator & Surgical Mask - Surgical Respirator
Sponsor[iv]	3M Australia Pty Ltd
Manufacturer[v]	3M Company 3M Healthcare dba 3M Consumer Health Care 3M Center
ARTG number[vi]	334581
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Anaphylactic reaction
Reported event outcome[xiv]	Injury
Report source category[xv]	Industry
Event type[xvi]	Patient Device Interaction Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	80036
Report date[ii]	29/06/2022
Trade name[iii]	3M Aura N95 P2 1870+ Particulate Respirator Surgical Mask Flat Fold
Sponsor[iv]	3M Australia Pty Ltd
Manufacturer[v]	3M Company 3M Healthcare dba 3M Consumer Health Care 3M Center
ARTG number[vi]	334581
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	3M Aura N95 P2 1870+ Particulate Respirator Surgic
Software version[xii]	-
Event description[xiii]	Nurse presented distressed, flushed, short of breath and reporting throat tightening.
Reported event outcome[xiv]	Injury
Report source category[xv]	Other
Event type[xvi]	Patient Device Interaction Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Dongguan Mayo Medical Technology Co Ltd - N95 Respirator - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

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Results

Number of reports: 1

Report number[i]	64504
Report date[ii]	23/07/2020
Trade name[iii]	N95 Respirator - Surgical/medical respirator, single-use
Sponsor[iv]	TRANSCEND INDUSTRIES PTY LTD
Manufacturer[v]	Dongguan Mayo Medical Technology Co Ltd
ARTG number[vi]	335026
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Split and holes observed in unused facemasks.
Reported event outcome[xiv]	No injury
Report source category[xv]	Consumer
Event type[xvi]	Material Integrity Problem, Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- ESound Medical Device Co Ltd - Medical Protective Mask, P2 Respirator - Public respirator, single-use - Public respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
- The DAEN - medical devices does not contain all known safety information about a particular medical device. Please do not make an assessment about the safety of a medical device based on the information in the DAEN - medical devices.

The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

About the release of this information

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Results

Number of reports: 1

Report number[i]	64963
Report date[ii]	21/08/2020
Trade name[iii]	Medical Protective Mask, P2 Respirator - Public respirator, single-use
Sponsor[iv]	ASPEN MEDICAL PTY LIMITED
Manufacturer[v]	ESound Medical Device Co Ltd
ARTG number[vi]	335542
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Wearing a P2 Mask that has been sterilised and smells strongly of Ethylene Oxide. Inhaling the fumes of the sterilisation agent.
Reported event outcome[xiv]	Injury
Report source category[xv]	Other
Event type[xvi]	Chemical Problem
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- SHENZHEN NITO POWER SOURCE TECHNOLOGY CO LTD - Joyroom - KN95 Mask - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
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About the Database of Adverse Event Notifications (DAEN) - medical devices

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The TGA medical device safety monitoring program

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- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

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Other useful sources of information on Australian medical devices

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Results

Number of reports: 1

Report number[i]	75683
Report date[ii]	31/01/2022
Trade name[iii]	Joyroom - KN95 Mask - Surgical/medical respirator, single-use
Sponsor[iv]	AKDA Global Exports Pty Ltd
Manufacturer[v]	SHENZHEN NITO POWER SOURCE TECHNOLOGY CO LTD
ARTG number[vi]	335543
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	JR-CY300
Software version[xii]	-
Event description[xiii]	KN95 masks were not stamped only had 3 layers instead of advertised 4 layers.
Reported event outcome[xiv]	No injury
Report source category[xv]	Consumer
Event type[xvi]	Manufacturing, Packaging or Shipping Problem, Labelling, Instructions for Use or Training Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- 3M United Kingdom Plc - P2 FFP2 BULK PACK Aura™ Flat Fold Particulate Respirator - Public respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

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Other useful sources of information on Australian medical devices

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Results

Number of reports: 1

Report number[i]	71796
Report date[ii]	2/09/2022
Trade name[iii]	P2 FFP2 BULK PACK Aura™ Flat Fold Particulate Respirator
Sponsor[iv]	3M Australia Pty Ltd
Manufacturer[v]	3M United Kingdom Plc
ARTG number[vi]	335620
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	9320A+
Software version[xii]	-
Event description[xiii]	A strap snapped.
Reported event outcome[xiv]	No injury
Report source category[xv]	Industry
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

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[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **3 medical devices** between **01/01/2020 – 31/12/2022**:

- Jiangsu SonaCare Medical Science & Technology Co Ltd - Premier - Mask, surgical, single use - Mask, surgical, single use
- Jiangsu SonaCare Medical Science & Technology Co Ltd - Premier - Surgical Procedural mask with ear loops (Level 2) - Mask, surgical, single use
- Jiangsu SonaCare Medical Science & Technology Co Ltd - Premier Surgical mask with loops - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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The TGA medical device safety monitoring program

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- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

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Results

Number of reports: 4

Report number[i]	64729
Report date[ii]	4/08/2020
Trade name[iii]	Premier - Surgical Procedural mask with ear loops (Level 2)
Sponsor[iv]	Bunzl Australia
Manufacturer[v]	Jiangsu SonaCare Medical Science & Technology Co Ltd
ARTG number[vi]	336935
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	BZFMELB/2
Software version[xii]	-
Event description[xiii]	Nurse found a dead embedded bug in unused mask.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Contamination / decontamination Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	64969
Report date[ii]	19/08/2020
Trade name[iii]	Premier Surgical mask with loops - Mask, surgical, single use
Sponsor[iv]	Bunzl Australia
Manufacturer[v]	Jiangsu SonaCare Medical Science & Technology Co Ltd
ARTG number[vi]	336935
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	BZFMELB/2
Software version[xii]	-
Event description[xiii]	Noxious odour - petrol/chemical smell
Reported event outcome[xiv]	
Report source category[xv]	Health Professional
Event type[xvi]	Contamination / decontamination Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	64970
Report date[ii]	19/08/2020
Trade name[iii]	Premier Surgical mask with loops - Mask, surgical, single use
Sponsor[iv]	Bunzl Australia
Manufacturer[v]	Jiangsu SonaCare Medical Science & Technology Co Ltd
ARTG number[vi]	336935
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	BZFMELB/2
Software version[xii]	-
Event description[xiii]	5 boxes contain a chemical smell.
Reported event outcome[xiv]	
Report source category[xv]	Health Professional
Event type[xvi]	Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Report number[i]	65133
Report date[ii]	28/08/2020
Trade name[iii]	Premier - Mask, surgical, single use
Sponsor[iv]	Bunzl Australia
Manufacturer[v]	Jiangsu SonaCare Medical Science & Technology Co Ltd
ARTG number[vi]	336935
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	BZFMELB/2
Software version[xii]	-
Event description[xiii]	6 complaints regarding skin irritation when masks are worn. 1 complaint regarding loose fitting mask.
Reported event outcome[xiv]	Injury
Report source category[xv]	Health Professional
Event type[xvi]	Material Integrity Problem, Patient Device Interaction Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

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[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **3 medical devices** between **01/01/2020 – 31/12/2022**:

- Lai Xin Underwear Co Ltd - M House Pty Ltd - Mask, surgical, single use - Mask, surgical, single use
- Lai Xin Underwear Co Ltd - Softmed (bought at Coles), "Surgical face mask" - Mask, surgical, single use - Mask, surgical, single use
- Lai Xin Underwear Co Ltd - Softmed branded surgical mask - Mask, surgical, single use

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You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

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Results

Number of reports: 3

Report number[i]	64408
Report date[ii]	17/07/2020
Trade name[iii]	Softmed branded surgical mask
Sponsor[iv]	M House Pty Ltd
Manufacturer[v]	Lai Xin Underwear Co Ltd
ARTG number[vi]	337122
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Poor quality: ear loops falling off from mask very easily even with light stretch. Front and backside: the same colour makes it hard to distinguish front and back (generally masks provide one side with fluid-resistant level) Further validation required for information regarding FR, BFE and certificate.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	66403
Report date[ii]	6/11/2020
Trade name[iii]	M House Pty Ltd - Mask, surgical, single use
Sponsor[iv]	M House Pty Ltd
Manufacturer[v]	Lai Xin Underwear Co Ltd
ARTG number[vi]	337122
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Uncontrollable coughing fits to the point of dry retching to expel what felt like particles in upper respiratory/nasal tracts when wearing the masks
Reported event outcome[xiv]	Injury
Report source category[xv]	Consumer
Event type[xvi]	Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Report number[i]	70626
Report date[ii]	20/06/2021
Trade name[iii]	Softmed (bought at Coles), "Surgical face mask" - Mask, surgical, single use
Sponsor[iv]	M House Pty Ltd
Manufacturer[v]	Lai Xin Underwear Co Ltd
ARTG number[vi]	337122
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Face mask caused reaction in nose, lips, and throat
Reported event outcome[xiv]	Injury
Report source category[xv]	Consumer
Event type[xvi]	Patient Device Interaction Problem
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
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Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- BYD Precision Manufacture Co Ltd - BYD disposable respirator - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
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About the Database of Adverse Event Notifications (DAEN) - medical devices

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The TGA medical device safety monitoring program

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Other useful sources of information on Australian medical devices

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Results

Number of reports: 1

Report number[i]	68382
Report date[ii]	26/02/2021
Trade name[iii]	BYD disposable respirator - Surgical/medical respirator, single-use
Sponsor[iv]	BYD AUSTRALIA PTY LTD
Manufacturer[v]	BYD Precision Manufacture Co Ltd
ARTG number[vi]	337767
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Component misaligned
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Manufacturing, Packaging or Shipping Problem
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Detmold Medical Pty Ltd - Detmold D95/D95+, P2/N95 Respirator - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

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- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
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About the Database of Adverse Event Notifications (DAEN) - medical devices

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The TGA medical device safety monitoring program

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Results

Number of reports: 1

Report number[i]	68049
Report date[ii]	9/02/2021
Trade name[iii]	Detmold D95/D95+, P2/N95 Respirator - Surgical/medical respirator, single-use
Sponsor[iv]	Detmold Medical Pty Ltd
Manufacturer[v]	Detmold Medical Pty Ltd
ARTG number[vi]	337768
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	D95/D95+
Software version[xii]	-
Event description[xiii]	P2/N95 respirators are tearing during donning, fit testing and during clinical use.
Reported event outcome[xiv]	
Report source category[xv]	Other
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **2 medical devices** between **01/01/2020 – 31/12/2022**:

- CleanSpace Technology Pty Ltd - CleanSpace Powered Air Purifying Respirator - HALO - Airway protection face mask - Airway protection face mask
- CleanSpace Technology Pty Ltd - Personal Respiratory Protection for Healthcare - Airway protection face mask - Airway protection face mask

Important information on the Database of Adverse Event Notifications – medical devices

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The TGA medical device safety monitoring program

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Results

Number of reports: 2

Report number[i]	63967
Report date[ii]	23/06/2020
Trade name[iii]	CleanSpace Powered Air Purifying Respirator - HALO - Airway protection face mask
Sponsor[iv]	CleanSpace Technology Pty Ltd
Manufacturer[v]	CleanSpace Technology Pty Ltd
ARTG number[vi]	338028
GMDN Term[vii]	Airway protection face mask
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	No
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Breach in infection control standards.
Reported event outcome[xiv]	
Report source category[xv]	Health Professional
Event type[xvi]	Contamination / decontamination Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	68576
Report date[ii]	9/03/2021
Trade name[iii]	Personal Respiratory Protection for Healthcare - Airway protection face mask
Sponsor[iv]	CleanSpace Technology Pty Ltd
Manufacturer[v]	CleanSpace Technology Pty Ltd
ARTG number[vi]	338028
GMDN Term[vii]	Airway protection face mask
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	CleanSpare Halo
Software version[xii]	-
Event description[xiii]	Clips on the breathing circuit were broken
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Electrical /Electronic Property Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

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[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **6 medical devices** between **01/01/2020 – 31/12/2022**:

- SOFTMED MANUFACTURING PTY LTD - Mask, surgical, single use - Mask, surgical, single use
- SOFTMED MANUFACTURING PTY LTD - Softmed level 3 surgical mask - Mask, surgical, single use - Mask, surgical, single use
- SOFTMED MANUFACTURING PTY LTD - Softmed Manufacturing Level 3 Surgical Face Mask with Ear Loop - Mask, surgical, single use - Mask, surgical, single use
- SOFTMED MANUFACTURING PTY LTD - SOFTMED Surgical Mask (ear loops), Level 3 Surgical Mask - Mask, surgical, single use - Mask, surgical, single use
- SOFTMED MANUFACTURING PTY LTD - SOFTMED, Level 3 Surgical Mask - Mask, surgical, single use - Mask, surgical, single use
- SOFTMED MANUFACTURING PTY LTD - Surgical face Masks Level 3 - Mask, surgical, single use - Mask, surgical, single use

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Results

Number of reports: 15

Report number[i]	64744
Report date[ii]	7/08/2020
Trade name[iii]	SOFTMED Surgical Mask (ear loops), Level 3 Surgical Mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Broken strap/loops.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	64852
Report date[ii]	7/08/2020
Trade name[iii]	SOFTMED, Level 3 Surgical Mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Adequate protection is not present as it doesn't fit and sides are open.
Reported event outcome[xiv]	
Report source category[xv]	Health Professional
Event type[xvi]	Protective Measures Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	64972
Report date[ii]	20/08/2020
Trade name[iii]	SOFTMED, Level 3 Surgical Mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	L3DFM-RSEA
Software version[xii]	-
Event description[xiii]	Multiple reports of ear loops pulling away form mask - entire boxes affected.
Reported event outcome[xiv]	
Report source category[xv]	Health Professional
Event type[xvi]	Mechanical Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	67102
Report date[ii]	14/12/2020
Trade name[iii]	Softmed Manufacturing Level 3 Surgical Face Mask with Ear Loop - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	780511
Software version[xii]	-
Event description[xiii]	Masks are too thin and loops are too loose
Reported event outcome[xiv]	Injury
Report source category[xv]	Other
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	67733
Report date[ii]	18/01/2021
Trade name[iii]	Softmed level 3 surgical mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	780511
Software version[xii]	-
Event description[xiii]	Unable to create seal, nose piece doesn't mould well.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Use of Device Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	67754
Report date[ii]	18/01/2021
Trade name[iii]	Softmed level 3 surgical mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	780511
Software version[xii]	-
Event description[xiii]	Mask fits poorly. Does not feel that it fits on the side near the cheeks. Ear loops too loose. mask feels thin. Boxy fit
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Report number[i]	67734
Report date[ii]	18/01/2021
Trade name[iii]	SOFTMED, Level 3 Surgical Mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	780511
Software version[xii]	-
Event description[xiii]	Poor nose seal, does not mould to nasal bridge, fogs glasses
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Use of Device Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	67736
Report date[ii]	18/01/2021
Trade name[iii]	SOFTMED, Level 3 Surgical Mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	No seal from nose bar. moves about & fogs
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Protective Measures Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	67738
Report date[ii]	18/01/2021
Trade name[iii]	SOFTMED, Level 3 Surgical Mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	780511
Software version[xii]	-
Event description[xiii]	Unable to fit
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Mechanical Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	67740
Report date[ii]	18/01/2021
Trade name[iii]	SOFTMED, Level 3 Surgical Mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	780511
Software version[xii]	-
Event description[xiii]	Poor fitting, doesn't mould to face, constantly moving when speaking
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Protective Measures Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	67741
Report date[ii]	18/01/2021
Trade name[iii]	SOFTMED, Level 3 Surgical Mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	780511
Software version[xii]	-
Event description[xiii]	Level 3 masks frequently break off ear loops, occasionally loose fibres are present in mask when donning.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Use of Device Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	67756
Report date[ii]	18/01/2021
Trade name[iii]	SOFTMED, Level 3 Surgical Mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	780511
Software version[xii]	-
Event description[xiii]	Poorly fitted mask.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Protective Measures Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	67759
Report date[ii]	18/01/2021
Trade name[iii]	SOFTMED, Level 3 Surgical Mask - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	780511
Software version[xii]	-
Event description[xiii]	White mask does not provide adequate protection and breaks during use.
Reported event outcome[xiv]	
Report source category[xv]	Health Professional
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	71251
Report date[ii]	21/07/2021
Trade name[iii]	Surgical face Masks Level 3 - Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	broken elastic before use and many more break when putting them on.
Reported event outcome[xiv]	No injury
Report source category[xv]	Consumer
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	76107
Report date[ii]	9/02/2022
Trade name[iii]	Mask, surgical, single use
Sponsor[iv]	SOFTMED MANUFACTURING PTY LTD
Manufacturer[v]	SOFTMED MANUFACTURING PTY LTD
ARTG number[vi]	339475
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Facemask loops break.
Reported event outcome[xiv]	No injury
Report source category[xv]	Consumer
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

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[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
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Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Life Biotech Pty Ltd - Clinical Supplies - kN95 masks - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
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The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

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- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

About the release of this information

While reasonable care is taken to ensure that the information is an accurate record of the adverse events reported to the TGA, the TGA does not guarantee or warrant the accuracy, reliability, completeness or currency of the information or its usefulness in achieving any purpose. To the fullest extent permitted by law, including but not limited to section 61A of the Therapeutic Goods Act 1989, the TGA will not be liable for any loss, damage, cost or expense incurred in or arising by reason of any person relying on this information.

Results

Number of reports: 1

Report number[i]	77822
Report date[ii]	1/04/2022
Trade name[iii]	Clinical Supplies - kN95 masks - Surgical/medical respirator, single-use
Sponsor[iv]	Life Biotech Pty Ltd
Manufacturer[v]	Life Biotech Pty Ltd
ARTG number[vi]	340123
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	No marking on masks or in packaging. Very thin.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Appropriate Term/Code Not Available, Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
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Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **10 medical devices** between **01/01/2020 – 31/12/2022**:

- Care Essentials Pty Ltd - Care Essentials - Medical Grade Respirator:CareFIT P2 / N95 (Regular) – MSK-004 - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use
- Care Essentials Pty Ltd - CARE ESSENTIALS COCOON MASK, PARTICULATE RESPIRATOR, FACE, P2/N95 FILTER, - Surgical/medical respirator, single-use
- Care Essentials Pty Ltd - Care Essentials MSK-002 - MASK, PARTICULATE RESPIRATOR, FACE, P2/N95 FILTER, - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use
- Care Essentials Pty Ltd - Care Essentials MSK-002 P2/N95 Respirator Mask - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use
- Care Essentials Pty Ltd - Cocoon - Cocoon MSK-002 N95/P2 - Mask, surgical, single use - Surgical/medical respirator, single-use
- Care Essentials Pty Ltd - Cocoon - Respirator Mask N95/P2 - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use
- Care Essentials Pty Ltd - Cocoon Mask Particulate Respirator, Face, N95/P2 - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use
- Care Essentials Pty Ltd - Cocoon MSK-002 N95/P2 - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use
- Care Essentials Pty Ltd - Cocoon P2/N95 Respirator - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use
- Care Essentials Pty Ltd - Mask - Particulate respirator, face, P2/N95 Filter - Surgical/medical respirator, single-use - Surgical/medical respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

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About the Database of Adverse Event Notifications (DAEN) - medical devices

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Results

Number of reports: 4

Report number[i]	77828
Report date[ii]	30/03/2022
Trade name[iii]	Cocoon - Respirator Mask N95/P2 - Surgical/medical respirator, single-use
Sponsor[iv]	Care Essentials Pty Ltd
Manufacturer[v]	Care Essentials Pty Ltd
ARTG number[vi]	340518
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	Care Essential
Software version[xii]	-
Event description[xiii]	Mask tears easily and straps snaps off when user applying masks.
Reported event outcome[xiv]	
Report source category[xv]	Other
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	80614
Report date[ii]	21/07/2022
Trade name[iii]	Care Essentials MSK-002 P2/N95 Respirator Mask - Surgical/medical respirator, single-use
Sponsor[iv]	Care Essentials Pty Ltd
Manufacturer[v]	Care Essentials Pty Ltd
ARTG number[vi]	340518
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	MSK-002
Software version[xii]	-
Event description[xiii]	Mask foam tearing / glued incorrectly on nose.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	81911
Report date[ii]	15/09/2022
Trade name[iii]	Cocoon P2/N95 Respirator - Surgical/medical respirator, single-use
Sponsor[iv]	Care Essentials Pty Ltd
Manufacturer[v]	Care Essentials Pty Ltd
ARTG number[vi]	340518
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	MSK002
Software version[xii]	-
Event description[xiii]	Evidence of attempted weld and adhesive tape/paper in the layers of the respirator.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Manufacturing, Packaging or Shipping Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	82519
Report date[ii]	12/10/2022
Trade name[iii]	Care Essentials MSK-002 - MASK, PARTICULATE RESPIRATOR, FACE, P2/N95 FILTER, - Surgical/medical respirator, single-use
Sponsor[iv]	Care Essentials Pty Ltd
Manufacturer[v]	Care Essentials Pty Ltd
ARTG number[vi]	340518
GMDN Term[vii]	Surgical/medical respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	MSK-002
Software version[xii]	-
Event description[xiii]	Face masks missing component.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Manufacturing, Packaging or Shipping Problem
Other medical devices reported as being used[xvii]	None

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[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Jiangyin Jinmao Aluminum Composite Panel Co Ltd - Werkomed Surgical Black Face Mask 3 Ply with Earloops - Mask, surgical, single use - Mask, surgical, single use

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About the release of this information

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Results

Number of reports: 1

Report number[i]	73072
Report date[ii]	15/10/2021
Trade name[iii]	Werkomed Surgical Black Face Mask 3 Ply with Earloops - Mask, surgical, single use
Sponsor[iv]	Shield Right Pty Ltd
Manufacturer[v]	Jiangyin Jinmao Aluminum Composite Panel Co Ltd
ARTG number[vi]	340970
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Single use face masks with pleats facing up on the outside and down on the face side.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Manufacturing, Packaging or Shipping Problem
Other medical devices reported as being used[xvii]	None

Footnotes

[i] A unique number that permits reference to a particular report.

[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Shenzhen Anhio Medical Technology Co Ltd - VYTAL - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
- The search results can not be used to determine the incidence or likelihood of an adverse event occurring.

About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
- The DAEN - medical devices does not contain all known safety information about a particular medical device. Please do not make an assessment about the safety of a medical device based on the information in the DAEN - medical devices.

The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

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Results

Number of reports: 1

Report number[i]	72958
Report date[ii]	6/10/2021
Trade name[iii]	VYTAL - Mask, surgical, single use
Sponsor[iv]	Eczanes Pharmaceuticals Pty Ltd
Manufacturer[v]	Shenzhen Anhio Medical Technology Co Ltd
ARTG number[vi]	341025
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Ear loop detaches on the slightest handling.
Reported event outcome[xiv]	No injury
Report source category[xv]	Consumer
Event type[xvi]	Material Integrity Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Ningbo Hongrui Medical Supplies Co Ltd - Tiger, KN95 Face Mask - Box of 20 - Surgical/medical respirator, single-use - Public respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

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- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
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About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
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The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

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Results

Number of reports: 1

Report number[i]	71203
Report date[ii]	19/07/2021
Trade name[iii]	Tiger, KN95 Face Mask - Box of 20 - Surgical/medical respirator, single-use
Sponsor[iv]	LYL Investment Pty Ltd
Manufacturer[v]	Ningbo Hongrui Medical Supplies Co Ltd
ARTG number[vi]	341457
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Face mask not follow TGA rules and regulations
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Insufficient Information
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

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[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- 3DAUSMED - Level 3 Surgical mask - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

The TGA uses adverse event reports to monitor the safety of medical devices. This is part of the ongoing monitoring and compliance activities undertaken by the TGA. <http://www.tga.gov.au/safety/daen-devices-monitoring.htm>

- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
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About the Database of Adverse Event Notifications (DAEN) - medical devices

- The DAEN - medical devices contains information from reports of adverse events that the TGA has received in relation to medical devices used in Australia since 1 July 2012.
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The TGA medical device safety monitoring program

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- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

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Other useful sources of information on Australian medical devices

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Results

Number of reports: 1

Report number[i]	70482
Report date[ii]	13/06/2021
Trade name[iii]	Level 3 Surgical mask - Mask, surgical, single use
Sponsor[iv]	3DAUSMED
Manufacturer[v]	3DAUSMED
ARTG number[vi]	368350
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	No Lot number OR date of Manufacture recorded device boxes.
Reported event outcome[xiv]	No injury
Report source category[xv]	Consumer
Event type[xvi]	Labelling, Instructions for Use or Training Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- FuJian YingDaWo Medical Technology Co Ltd - Endeavour - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
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About the Database of Adverse Event Notifications (DAEN) - medical devices

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The TGA medical device safety monitoring program

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- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

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Results

Number of reports: 1

Report number[i]	63256
Report date[ii]	5/05/2020
Trade name[iii]	Endeavour - Mask, surgical, single use
Sponsor[iv]	Zenpharm Pty Ltd
Manufacturer[v]	FuJian YingDaWo Medical Technology Co Ltd
ARTG number[vi]	332554
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	No
Model number[xi]	SFM20-01
Software version[xii]	-
Event description[xiii]	The ear loop is not strong enough to secure the mask on user. Nose clip also comes out of the first layer.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Use of Device Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Hubei Wanli Protective Products Co Ltd - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
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Results

Number of reports: 1

Report number[i]	63215
Report date[ii]	30/04/2020
Trade name[iii]	Mask, surgical, single use
Sponsor[iv]	GSW Group Pty Ltd
Manufacturer[v]	Hubei Wanli Protective Products Co Ltd
ARTG number[vi]	333192
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Concerns that device does not comply with TGA regulations.
Reported event outcome[xiv]	No injury
Report source category[xv]	Other
Event type[xvi]	Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **2 medical devices** between **01/01/2020 – 31/12/2022**:

- 3M Company 3M Healthcare dba 3M Consumer Health Care 3M Center - 1860 3M Cupped Particulate Respirator & Surgical Mask - Surgical Respirator - Public respirator, single-use
- 3M Company 3M Healthcare dba 3M Consumer Health Care 3M Center - 3M Aura N95 P2 1870+ Particulate Respirator Surgical Mask Flat Fold - Public respirator, single-use

Important information on the Database of Adverse Event Notifications – medical devices

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- An adverse event report does not mean that the medical device is the cause of the adverse event. <http://www.tga.gov.au/safety/daen-devices-about.htm>
- If you are experiencing an adverse event, or think you may be experiencing one, please seek advice from a health professional as soon as possible. <http://www.healthdirect.org.au/>
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About the Database of Adverse Event Notifications (DAEN) - medical devices

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The TGA medical device safety monitoring program

More information about the DAEN - medical devices and the TGA medical devices safety monitoring program is available at:

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- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

You are encouraged to report an adverse event or a near (potential) adverse event associated with the use of a medical device used in Australia. <http://www.tga.gov.au/safety/daen-devices-qa.htm> Reports of adverse events in relation to medical devices can be reported using the online reporting forms, by email, fax and mail. <http://www.tga.gov.au/safety/problem.htm>

Other useful sources of information on Australian medical devices

More information about a medical device is generally available in the instructions for use and/or on the labelling and packaging of a medical device. Your health professional can also provide help and assistance on how to use medical devices. Information on a range of health and wellbeing topics including medical devices is available from healthinsite <http://www.healthinsite.gov.au/>

About the release of this information

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Results

Number of reports: 2

Report number[i]	71045
Report date[ii]	5/08/2021
Trade name[iii]	1860 3M Cupped Particulate Respirator & Surgical Mask - Surgical Respirator
Sponsor[iv]	3M Australia Pty Ltd
Manufacturer[v]	3M Company 3M Healthcare dba 3M Consumer Health Care 3M Center
ARTG number[vi]	334581
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Anaphylactic reaction
Reported event outcome[xiv]	Injury
Report source category[xv]	Industry
Event type[xvi]	Patient Device Interaction Problem
Other medical devices reported as being used[xvii]	None

Report number[i]	80036
Report date[ii]	29/06/2022
Trade name[iii]	3M Aura N95 P2 1870+ Particulate Respirator Surgical Mask Flat Fold
Sponsor[iv]	3M Australia Pty Ltd
Manufacturer[v]	3M Company 3M Healthcare dba 3M Consumer Health Care 3M Center
ARTG number[vi]	334581
GMDN Term[vii]	Public respirator, single-use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	3M Aura N95 P2 1870+ Particulate Respirator Surgic
Software version[xii]	-
Event description[xiii]	Nurse presented distressed, flushed, short of breath and reporting throat tightening.
Reported event outcome[xiv]	Injury
Report source category[xv]	Other
Event type[xvi]	Patient Device Interaction Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

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[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

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[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Intco Medical HK Co Ltd - Thermo Fisher Scientific Australia Pty Ltd Disposable Face Mask blue 175mm x 95mm - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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The TGA medical device safety monitoring program

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- About the DAEN - medical devices <http://www.tga.gov.au/safety/daen-devices-about.htm>
- Medical devices safety <http://www.tga.gov.au/safety/information-devices.htm>

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Other useful sources of information on Australian medical devices

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Results

Number of reports: 1

Report number[i]	63504
Report date[ii]	26/05/2020
Trade name[iii]	Thermo Fisher Scientific Australia Pty Ltd Disposable Face Mask blue 175mm x 95mm
Sponsor[iv]	Thermo Fisher Scientific Australia Pty Ltd
Manufacturer[v]	Intco Medical HK Co Ltd
ARTG number[vi]	335121
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Wire used to shape the mask across the bridge of one's nose is so flimsy that it does not retain the shape sufficiently.
Reported event outcome[xiv]	No injury
Report source category[xv]	Consumer
Event type[xvi]	Use of Device Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[ii] The date that TGA received the finalised report.

[iii] The trade name is the name under which the medical device is sold. This is also known as the brand name.

[iv] The person or company responsible for the supply in and/or exportation from Australia of a therapeutic product. Sponsors must hold an ARTG licence for these products, unless exempted.

[v] The person or company responsible for the design, production, packaging and labelling of a therapeutic product before it is supplied under their name.

[vi] The entry number on the Australian Register of Therapeutic Goods (ARTG). Therapeutic products must be entered on the ARTG before they can be lawfully supplied in Australia.

[vii] A description of the medical device as defined by the Global Medical Device Nomenclature system.

[viii] The medical devices regulatory framework has a classification system for medical devices. The classification is based on the relative risk of the device.

[ix] The manufacturer has indicated the medical device has been designed, produced and packaged in a way that ensures it is sterile when supplied.

[x] The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

[xi] The alphanumeric code assigned by the manufacturer to identify a specific product type.

[xii] The alphanumeric code assigned by the manufacturer to identify a specific release of a program.

[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Foshan Nanhai Plus Medical Co Ltd - Foshan medical sugical mask - Mask, surgical, single use - Mask, surgical, single use

Important information on the Database of Adverse Event Notifications – medical devices

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Other useful sources of information on Australian medical devices

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Results

Number of reports: 1

Report number[i]	63817
Report date[ii]	16/06/2020
Trade name[iii]	Foshan medical sugical mask - Mask, surgical, single use
Sponsor[iv]	Austherapy Pty Ltd
Manufacturer[v]	Foshan Nanhai Plus Medical Co Ltd
ARTG number[vi]	335231
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1
Sterile[ix]	No
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Mask missing nose wire.
Reported event outcome[xiv]	No injury
Report source category[xv]	Health Professional
Event type[xvi]	Manufacturing, Packaging or Shipping Problem
Other medical devices reported as being used[xvii]	None

Footnotes

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[xiii] A description of the adverse event.

[xiv] A description of the outcome reported to have been caused by the adverse event.

[xv] A general category describing the type of person who made the report.

[xvi] General categories describing the type of adverse event as defined in the ISO/TS 19218-1:2011 - Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes.

[xvii] A list of other medical devices reported to be associated with the adverse event.

Australian Government
Department of Health
Therapeutic Goods Administration

Database of Adverse Event Notifications - medical devices

List of reports

You searched for the following **1 medical device** between **01/01/2020 – 31/12/2022**:

- Jiangsu Traumark Medical Instrument Co Ltd - Traumark Medical - Mask, surgical, single use - Mask, surgical, single use

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Results

Number of reports: 1

Report number[i]	63467
Report date[ii]	22/05/2020
Trade name[iii]	Traumark Medical - Mask, surgical, single use
Sponsor[iv]	Plusrite Australia Pty Ltd
Manufacturer[v]	Jiangsu Traumark Medical Instrument Co Ltd
ARTG number[vi]	335581
GMDN Term[vii]	Mask, surgical, single use
Device classification[viii]	Class 1 Sterile
Sterile[ix]	Yes
Single use[x]	Yes
Model number[xi]	-
Software version[xii]	-
Event description[xiii]	Concerns device are not fit for purpose and do not comply with the TGA regulations.
Reported event outcome[xiv]	Injury
Report source category[xv]	Other
Event type[xvi]	Appropriate Term/Code Not Available
Other medical devices reported as being used[xvii]	None

Footnotes

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[xvii] A list of other medical devices reported to be associated with the adverse event.