Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods Administration

Annual performance statistics report

2019-20

Contents

About the Therapeutic Goods Administration

The Australian Government Department of Health, through the Therapeutic Goods Administration (TGA), is responsible for assessing whether therapeutic goods available for supply in Australia are safe and fit for their intended purpose.

Products for which therapeutic claims are made are assessed by the TGA and entered on the Australian Register of Therapeutic Goods (ARTG). At 30 June 2020 there were 92,060 therapeutic goods on the ARTG, including 9,652 new products added during the reporting period. All therapeutic goods registered on the ARTG can be lawfully manufactured and supplied in Australia and include prescription medicines, over-the-counter medicines, complementary medicines, biologicals, and medical devices.

The TGA regulates the supply of:

- medicines prescribed by a doctor or dentist
- medicines available from behind the pharmacy counter
- medicines available in the general pharmacy
- medicines available from retail outlets
- complementary medicines, such as vitamins, herbal and traditional medicines
- medical devices, from simple devices like bandages to complex technologies like heart pacemakers
- products used to test for various diseases or conditions (in vitro diagnostic devices (IVDs)), such as blood tests
- vaccines, blood products, and other biologicals.

We play a regulatory role in overseeing the manufacturing process and advertising of therapeutic goods. We support compliance with the regulatory framework, working with state, territory and federal counterparts to remove unsafe/non-compliant therapeutic goods from the Australian market.

More information about how therapeutic goods are regulated in Australia can be found on our website (www.tga.gov.au).

Executive Summary

Each year we provide information about our regulatory performance through the *TGA Annual Performance Statistics Report* and the *Half Yearly Performance Snapshot*. We also report annually on our performance against the *Regulator Performance Framework* through the *TGA Self-Assessment (Key Performance Indicators) Report*.

The statistics contained within this report cover the period 1 July 2019 to 30 June 2020, and contribute to annual publications that track our progress against the priorities we have established for the financial year.

Performance Highlights

Key observations for 2019-20 are summarised below, including trends and notable changes from previous reporting periods.

Impacts of COVID-19

- General inquiries to the TGA increased by 250% in April of 2020 compared to the same time in previous years. There was also a similar increase in contact to the specialised enquiry lines including in relation to Medicines Shortages which saw a 300% increase in enquiries and Medical Devices which saw call volumes increase by over 200% over the March-June 2020 period.

Medical device approvals

- The COVID-19 pandemic has disrupted normal application assessment processes due to the higher than average number of medical device (including in-vitro diagnostic) and Other Therapeutic Goods (OTG) disinfectant applications received. Processing times are longer than the comparable period in previous years, but remain within legislative timeframes.
- The TGA undertook an expedited assessment process for medical devices and OTG applications related to COVID-19 pandemic to ensure that patients and healthcare providers had timely and continued access to quality medical devices and OTG disinfectants to respond efficiently to the COVID-19 pandemic.
- In response to the COVID-19 pandemic, exemptions from the normal requirements of assessment and inclusion on the ARTG under section 41GS of the *Therapeutic Goods Act 1989* (the Act) were enacted by the Health Minister on advice from the TGA for certain medical devices. These exemptions include:
  - face mask exemption (applies to disposable face masks, gloves, gowns, and protective eye wear *"designed to be worn by individuals to prevent the transmission of organisms"*
  - ventilator exemption (applies to hospital ventilators manufactured in Australia)
  - pathology exemption (applies to in-vitro diagnostic (IVD) medical devices).
- The TGA also introduced two expedited assessment pathways to legally supply COVID-19 pandemic related IVD test kits.

Laboratory testing

- Much of the laboratory testing work, including all laboratory bench work, could not be relocated. Our laboratories continued normal operations with reduced staff numbers on-site where possible.

- With travel and transport restrictions in place, limitations were placed on the purchasing of test samples, and the installation and servicing of instruments.
- Laboratory staff were directly involved in providing advice and developing strategies around various pandemic-related issues, as well as providing assistance to other areas of the TGA.

Medicine shortages/discontinuations

- There was a sharp increase in demand for medicines in March 2020, as consumers and pharmacists purchased additional quantities of medicines in response to the COVID-19 pandemic. As a result, the TGA received a markedly increased number of shortage notifications in April (282 new shortages, compared with an average of 150 per month during 2019). Many of these notifications were for shortages that sponsors expected would occur in the future if demand remained elevated. The effect of increased demand on shortage notifications was short-lived, with 138 new shortages notified to the TGA in May.
- In April and May 2020, the TGA granted 49 section 19A approvals to supply an overseas-registered product to address a shortage, compared with an average of 10 per month for the 2019 calendar year. Approvals were granted to ensure adequate and continuing supply of critical medicines subject that where likely to be subject to increased demand due to the pandemic.
- The TGA has worked closely with medicine sponsors, health professional groups, industry and wholesaler peak bodies and other government departments to ensure a coordinated and proactive approach to managing medicine supply during the pandemic, including:
  - convening more frequent, weekly, meetings of the Medicine Shortages Working Party, to identify and develop coordinated solutions to medicine shortage issues arising from the COVID-19 pandemic. 14 meetings were held in the first half of 2020
  - releasing a joint statement with the Pharmacy Guild of Australia and the Pharmaceutical Society of Australia requesting pharmacists to limit dispensing and sales of medicines, to support fair and equitable access to medicines
  - convening meetings of groups of sponsors to explore coordinated approaches to managing supply of critical medicines, under an authorisation granted by the Australian Competition and Consumer Commission
  - working with the Department of Foreign Affairs and Trade and Austrade to facilitate solutions to export restrictions and logistics issues affecting medicine supply
  - receiving regular data on supply of critical medicines from sponsors to support ongoing monitoring
  - implementing a new shortage management action, the Serious Shortage Substitution Notice, to allow pharmacists to substitute a different strength or dose form for a medicine in shortage without prior approval from the prescribing doctor
  - working with state and territory health departments to model demand for medicines required for intensive care management of COVID-19 pandemic patients, to assist in ensuring adequate supply of these medicines.

Recalls

- During the initial months of the COVID-19 pandemic, the number of sponsor recall notifications remained consistent overall with notifications received during other periods. Where recall actions have involved products which are used for the treatment of COVID-19 pandemic patients,

additional risk-benefit considerations have been taken into account to balance the risk posed by the product defect relative to the risk of the product not being available for treatment at all and/or a shortage situation being created.

Over-the-Counter Medicines

- The COVID-19 pandemic has resulted in increased usage and demand for hand sanitiser products, with enquiry volume increasing by 180% during March-June 2020. A temporary exemption for specified hand sanitisers was established in March 2020 to facilitate the urgent supply of hand sanitisers in Australia due to the increased demand. Specified hand sanitisers have been excluded from TGA regulation provided they contain only particular ingredients in particular quantities, comply with certain manufacturing practices, and comply with certain advertising, labelling and presentation requirements. The *Therapeutic Goods (Excluded Goods - Hand Sanitisers) Determination 2020* outlines the exclusion requirements.
- We received a significant increase in the number of enquiries relating to the regulation of Over the Counter (OTC) medicines, particularly in relation to hand sanitisers.
- The supply of some crucial OTC medicines, such as paediatric paracetamol preparations and TGA approved hand sanitiser products, has been adversely effected by the COVID-19 pandemic due to impacts on overseas manufacturers, and shortages of ingredients and packaging materials. As a consequence, resources were directed to expediting applications for affected products that sought to change the approved details for their products.
- A significant increase in enquiries and the redirection of resources has impacted the performance statistics for some OTC medicine application levels. For N3 and N4 applications, the percentage of applications processed within the target time was below 80%.

Good Manufacturing Practice

- In March 2020, following the Prime Minister's announcement for all Australians to reconsider their need to travel internationally, the TGA reviewed all planned overseas inspections. In line with international regulators, all international inspections were postponed until further notice, which is reflected in the decline of inspections conducted. Affected sponsors were contacted about this decision, which did not affect supply of critical medicines.
- To ensure the TGA was responsive to the COVID-19 pandemic situation, the approach to Good Manufacturing Practice (GMP) inspection processes was revised.
- The domestic GMP inspections program continued to be delivered either via a remote domestic inspection or a hybrid inspection with remote and onsite components. Where there was an onsite component, each inspection underwent a detailed risk assessment of COVID-19 pandemic and workplace health and safety preparedness prior to confirmation of attendance with manufacturers. In some cases, conditions have been added to manufacturing licences issued until a follow-up inspection is undertaken at a later time. The outcomes of these revised arrangements are being actively monitored.
- There was an increase in the number of GMP clearance applications received as a result of COVID-19 pandemic. This was attributed to the suspension of overseas GMP inspections in March 2020 as well as a number of alternative manufacturers requiring approval to meet increased demand of their products.
- Difficulties arose in obtaining supplies of some therapeutic goods. One example related to the timely supply of radiopharmaceuticals and radiopharmaceutical active ingredients (RAI) from a licensed manufacturer. To address this issue, on 2 May 2020 an amendment to the Therapeutic

Goods Regulations (1990) Schedule 7, Part 3-3 was made to exempt certain radiopharmaceuticals and RAI to enable specified persons, within public and private hospitals and public institutions without a manufacturing licence, to manufacture radiopharmaceuticals or RAI for the treatment of a patient in another State or Territory.

International collaborations

- The COVID-19 pandemic saw an increased dialogue and collaboration between international regulators. The TGA has been meeting fortnightly with a network of all major global regulators about COVID-19 pandemic, where current clinical trials and usage of the latest medicines and therapies are discussed, leading to a joint understanding and potential partnerships in rapid evaluations.

Compliance

- In March 2020 the TGA COVID-19 Enforcement Taskforce was established to focus on compliance activity specific to therapeutic goods regulation during the COVID-19 pandemic. The taskforce focussed on education and non-compliance preventative measures through to enforcement action, such as the issue of infringement notices, where necessary. Between March and 31 July 2020, the TGA issued 58 infringement notices totalling $573,840 for alleged offences relating to COVID-19 and advertising requirements under therapeutic goods legislation, and has since initiated court action for one of these cases. Preventing, detecting and addressing non-compliance with The Act related to goods being imported, manufactured, supplied, exported and advertised in relation to COVID-19 pandemic continues to be a priority. Further information is available in the Therapeutic Goods Advertising Compliance Annual Report[a].

Reforms

Prescription medicines

- Despite an increase in volume (from 349 in 2018-19 to 373 in 2019-20), there have been substantial improvements in the assessment times for Category 1 applications. Over the last financial year the median assessment time has fallen from 182 working days to 162.
- During this reporting period, the TGA:
  - decided 19 medicines were eligible for priority review
  - approved 29 medicines with an orphan drug designation and six medicines with a priority review approval for registration, with a median approval time of 133 working days
  - approved 10 medicines given provisional determination for registration, with a median approval time of 135 working days
  - approved two medicines for registration after undergoing Comparable Overseas Regulator (COR)-A review with a median approval time of 109 working days
  - approved eight medicines for registration after undergoing Comparable Overseas Regulator (COR)-B review with a median approval time of 161 working days
  - reviewed four medicines collaboratively through work-sharing arrangements with the Australia-Canada-Singapore-Switzerland Consortium (ACSS)

[a] www.tga.gov.au/resource/therapeutic-goods-advertising-compliance-2019-20-annual-report

  - Reviewed four medicines collaboratively through the United Stated Food and Drug Administration's Project Orbis.

- The new streamlined AusPAR process implemented in September 2019 has seen a large increase in the number of AusPARs published (89 as compared to 62 in the previous year). We have also published 35 Prescription Medicine Decision Summaries since their introduction in September 2019.

- Following an extensive consultation process, implementation of a range of regulatory reforms relating to opioids began in October 2019. These reforms include: requirements for sponsors to register additional smaller pack sizes for immediate-release products; updates to information and required warnings for health professionals and consumers; and tighter restrictions on indications. TGA funded a range of stakeholders to undertake change and adoption activities and undertook broad-ranging market research into attitudes and expectations around opioid use among both health professionals and consumers. Implementation of the reforms will continue in 2020-21.

Work sharing with overseas regulators

- The TGA, Health Canada and the Swiss Agency for Therapeutic Products (Swissmedic) jointly evaluated and then approved Xofluza (Baloxavir marboxil)™, a treatment for uncomplicated influenza in certain populations, making it the first time in the initiative where three regulators have work-shared and the first time Australia has work-shared with Swissmedic.

Listed medicines

- The new assessed listed medicines pathway for listing on the ARTG was introduced in March 2018 following the Government's response to Recommendations from the Expert Review of Medicines and Medical Devices Regulation. Three applications were received via this pathway in 2019-20, and they are currently under evaluation.

- A database of listed medicine compliance review results was implemented on the TGA website. The outcomes of all compliance reviews have been published quarterly since December 2019.

Increased transparency

- We amended the public summaries of medicines and biologicals on the Australian Register for Therapeutic Goods (ARTG) to include the names of excipient ingredients. This will assist Australians in making informed choices about their medicines and biologicals, particularly those trying to avoid substances that cause allergic reactions. Comprehensive communications to assist consumers' understanding of how to access and interpret information about excipients has accompanied the launch in April. This included a new "what ingredients are in my medicines" section on the TGA website, and posts on TGA's social media channels advising of the changes and access to further information.

Medicine and vaccine adverse event reports

- During this period, we received a total of 24,898 medicine and vaccine adverse event reports (4,103 reports related to vaccines). The mean number of reports received weekly by the TGA was 479. Of the accepted cases, 61% (14,418) were submitted by pharmaceutical companies and 20% (4,744) were made by health professionals. The most prolific reporters among health professionals were pharmacists (including hospital pharmacists) with 2363 reports submitted.

- During this period, 12 additional pharmaceutical companies transitioned to using the Electronic Data Interchange (EDI) which enables submission of adverse event reports directly into the TGA's

database. This brings the total number of sponsors using the EDI to 34, with 68% of reports received from pharmaceutical companies submitted via the EDI.

Biologicals

- Increased activity around Class 4 biologicals related to approval of several CAR-T cell products, and constant product improvement and manufacturing capacity expansion within the sector.

Laboratory testing

- Significant amendments to Part 5 of the Therapeutic Goods Regulations 1990 were implemented in January 2020. Part 5 describes the TGA's legal requirements regarding the examination, testing and analysis of goods, including requirements regarding the reporting of test results.

Recalls

- Overall, the total number of recall actions remained similar to that of the last financial year with a slight increase.
- There was a significant increase (33%) of recall actions performed for medicines. This was primarily due to a large number of recalls performed for ranitidine products in September and October 2019, regarding trace amounts of N-nitrosodimethylamine (NDMA) impurities in these medicines.
- Recall actions for biological products have decreased this financial year from 29 to 16.
- A new enhancement has been added to the System for Australian Recall Actions (SARA) database on the TGA website, in response to requests from industry and other external stakeholders to provide better access to TGA recall data. The new feature allows users to extract individual search data into editable, MS Excel spreadsheets, and includes all of the existing, publically available data in SARA in an easy to use format. This will provide enhanced access and transparency through users acquiring 'self-serve' style, ready access to large volumes of recall action data.

Medicine shortages/discontinuations

- In December 2019, at the request of the Minister for Health, the Department reconvened the Medicine Shortage Working Party to discuss the operation of the medicine shortages scheme during the first year of mandatory shortage reporting. The Working Party made recommendations to the TGA relating to improving monitoring, communication and management of medicine shortages. The TGA is progressing these recommendations, including:
  - submitting a proposal to improve transparency of shortage notifications for advice from the Working Party
  - improving communications about medicine shortages, including revising information for health professionals and consumers on the TGA website, expanding the scope of the weekly medicine shortages alert and developing a comprehensive stakeholder engagement strategy to guide further activities
  - implementing communiqués to provide advice to health professionals about important shortages, with the first communiqué, about the discontinuation of the antidepressant Nardil (phenelzine), published in June 2020.

Processing and Approval Times

Processing and approval times are defined as the number of working days from the acceptance of an application until formal notification of decision, unless otherwise specified. These exclude times where we were unable to progress the application due to waiting for:

- the sponsor to provide additional information;
- the payment of fees; or
- a 'mutual clock stop' period, agreed with the applicant or unless otherwise specified.

Under the Act, TGA working days also excludes public holidays and weekends. The timeframes applicable to many of our activities are mandated by legislation. For other activities we conduct we self-impose target timeframes, to ensure that we perform our functions efficiently and in a timely manner. Target timeframes are subject to ongoing review.

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. The priority review pathway (applicable to Category 1 applications only) has the same statutory timeframe as other Category 1 applications, but the target timeframe is 150 working days.
Comparable Overseas Regulator (COR) report-based process *(from 1 January 2018)*	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 to notify the applicant 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. The amount and type of any additional data requiring evaluation, as well as the age of the assessment report, will determine whether the application is best processed under the COR-B approach or as a standard Category 1 application.

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 (SRR)	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 (SAR)	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 2019 to June 2020

	Number			
Application Type	Approved	Withdrawn	Rejected	Total (% Approved)
Category 1				
A: New chemical entity/New biological entity/Biosimilar[a]	38	1	0	39 (97%)
B: New fixed-dose combination	7	0	0	7 (100%)
C: Extension of indication	58	2	2	62 (94%)
D: New generic medicine	82	2	0	84 (98%)
F: Major variation	53	3	1	57 (93%)
G: Minor variation[b]	2	0	0	2 (100%)
H: Minor variation[c]	15	0	0	15 (100%)
J: Changes to Product Information	118	2	0	120 (98%)
Comparable Overseas Regulator (COR) – A				
A: New chemical entity/New biological entity/Biosimilar	1	0	0	1 (100%)
C: Extension of indication	1	0	0	1 (100%)
Comparable Overseas Regulator (COR) – B				
A: New chemical entity/New biological entity/Biosimilar	3	0	0	3 (100%)
C: Extension of indication	2	0	0	2 (100%)
D: New generic medicine	1	0	0	1 (100%)
F: Major variation	2	0	0	2 (100%)
Minor Variations				
Category 3				
G: Minor variation[b]	104	5	0	109 (95%)
H: Minor variation[c]	1311	21	0	1332 (98%)
Additional trade name [ATN]	50	0	0	50 (100%)
Extension of Indications - Generic	6	0	0	6 (100%)
Safety-related request [SRR]	1054	23	0	1077 (98%)
Self-assessable request [SAR]	1126	12	0	1138 (99%)
Minor editorial change [MEC]	296	7	0	303 (98%)
Correction [9D(1)]	165	18	0	183 (90%)
Notification	1588	13	0	1601 (99%)
Total	6083	109	3	6195 (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

	2018-19	2019-20
	July to June	
Consent to supply/import/export when not conforming to a standard [S.14 and S.14A]	Number (% of Total)	
Approved	62 (98%)	93 (100%)
Rejected	1 (2%)	0 (0%)
Total (excluding withdrawals)	63 (100%)	93 (100%)

1.2. Approval times

Table 3 Prescription medicine application approval time for July 2019 to June 2020

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]	33	255	190	196	35-247
B: New fixed-dose combination	7	255	186	184	155-228
C: Extension of indication[b]	57	255	176	185	40-250
D: New generic medicine	82	255	173	160	96-254
F: Major variation	53	255	180	186	61-252
G: Minor variation	2	255	220	220	214-226
H: Minor variation	15	255	119	112	57-220
J: Changes to Product Information requiring the evaluation of data	118	255	124	122	10-255
Comparable Overseas Regulator (COR-A)					
A: New chemical entity/New biological entity/Biosimilar	1	120	104	104	N/A
C: Extension of indication	1	120	115	115	N/A
Comparable Overseas Regulator (COR-B)					
A: New chemical entity/New biological entity/Biosimilar	3	175	138	168	73-173
C: Extension of indication	2	175	164	164	158-171
D: New generic medicine	1	175	164	164	164-164
F: Major variation	2	175	147	147	143-152

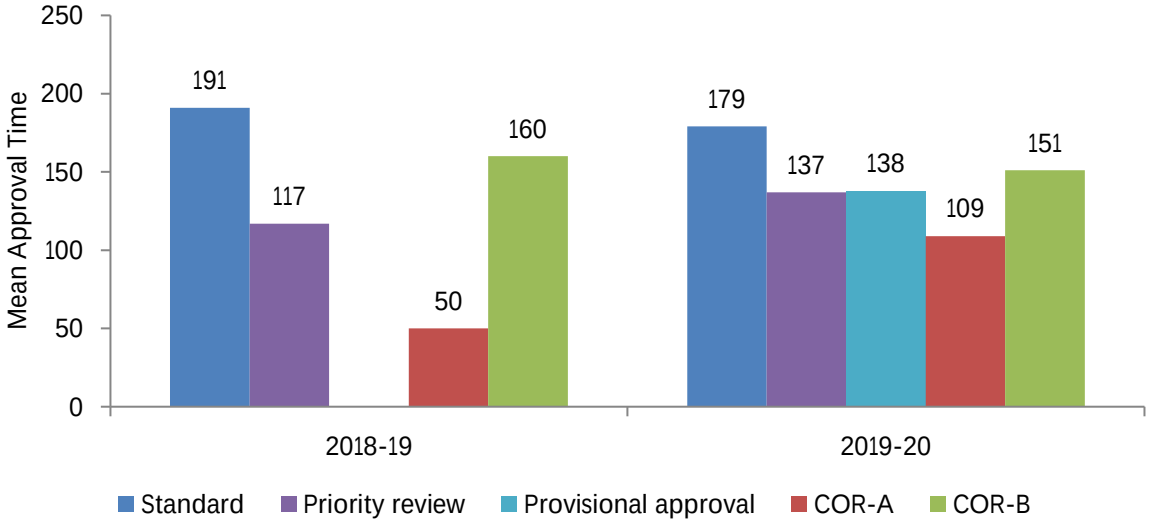
[a] Application type A figures do not include one submissions processed via the priority review pathway.
[b] Application type C figures do not include five submissions processed via the priority review pathway.

Table 4 Prescription medicine median approval time comparisons

Application type	Legislated timeframe	Median approval time (TGA working days)	
		2018-19	2019-20 (% Change)
Category 1			
A: New chemical entity/New biological entity/Biosimilar[a]	255	202	196 (▼3%)
B: New fixed-dose combination	255	198	184 (▼7%)
C: Extension of indication[b]	255	197	186 (▼6%)
D: New generic medicine	255	170	159 (▼7%)
F: Major variation	255	194	186 (▼4%)
G: Minor variation	255	223	220 (▼1%)
H: Minor variation	255	81	112 (▲39%)
J: Changes to Product Information requiring the evaluation of data	255	141	123 (▼13%)
Comparable Overseas Regulator (COR) – A			
A: New chemical entity/New biological entity/Biosimilar	120	n/a	104
C: Extension of indication	120	40	115 (▲188%)
Comparable Overseas Regulator (COR) – B			
A: New chemical entity/New biological entity/Biosimilar	175	172	168 (▼2%)
C: Extension of indication	175	161	165 (▲2%)
D: New generic medicine	175	n/a	164
F: Major variation	175	146	148 (▲1%)
Minor Variations			
Category 3			
G: Minor variation[c]	45	40	38 (▼5%)
H: Minor variation[d]	45	36	32 (▼11%)
Additional trade name [ATN]	45	41	30 (▼27%)
Extension of Indications - Generic	45	45	38 (▼16%)
Safety-related request [SRR]	N/A	36	37 (▲3%)
Self-assessable request [SAR]	45	38	39 (▲3%)
Minor editorial change [MEC]	45	30	34 (▲13%)
Correction [9D(1)]	N/A	56	74 (▲32%)

[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.

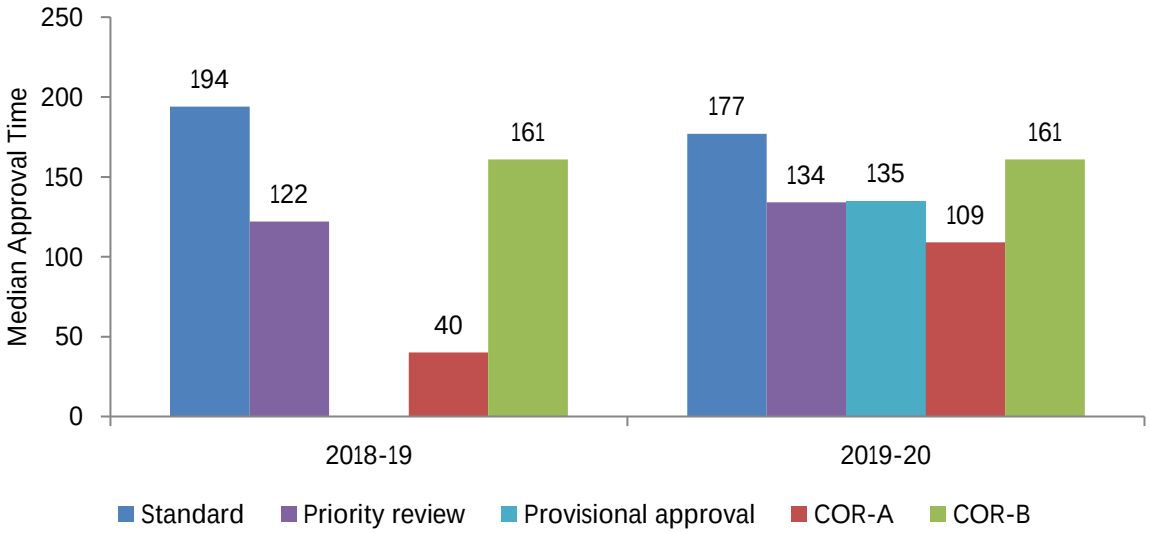
Figure 1 Mean approval times (TGA working days) for submissions [a] by pathway 2018-19 [b] and 2019-20



[a] For new chemical entities, new combinations, extension of indications, new generic medicines and major variations. During these periods, volumes of submission approvals for 2018-19 and 2019-20 were: standard - 232 and 223, priority review - 11 and 6, provisional approval - 0 and 10, COR-A - 3 and 2 and COR-B - 3 and 8, respectively.

[b] Provisional approval mean timeframes were not reported in 2018-19.

Figure 2 Median approval times (TGA working days) for submissions [a] by pathway 2018-19 [b] and 2019-20



[a] For new chemical entities, new combinations, extension of indications, new generic medicines and major variations. During these periods, volumes of submission approvals for 2018-19 and 2019-20 were: standard - 232 and 223, priority review - 11 and 6, provisional approval - 0 and 10, COR-A - 3 and 2 and COR-B - 3 and 8, respectively.

[b] Provisional approval median timeframes were not reported in 2018-19.

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 designations

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Application type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	16 (67%)	22 (76%)
C: Extension of indications	7 (29%)	6 (21%)
F: Major variation	1 (4%)	1 (3%)
Total	24 (100%)	29 (100%)

Table 6 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.

	2018-19		2019-20	
	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	8[a] (36%)	163	12 (57%)	184
C: Extension of indications	7 (32%)	212	9 (43%)	175
F: Major variation	7 (32%)	194	0 (0%)	N/A
Total	22[a] (100%)	190	21 (100%)	181

a Two new biological entities were registered under the new orphan drug program and the priority review pathway, one new chemical entity was registered under the new orphan drug program and the COR-B review pathway.

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 7 Number of priority review determinations granted

	2018-19	2019-20
	July-June	
	Number (% of Total)	
Application type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	6 (67%)	6 (60%)
C: Extension of indications	3 (33%)	4 (40%)
Total	9 (100%)	10 (100%)

Table 8 Number of medicines approved through the priority review pathway[a]

	2018-19		2019-20	
	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 (27%)	129	5 (83%)	137
C: Extension of indications	8 (73%)	121	1 (17%)	105
Total	11 (100%)	122	6 (100%)	133

[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 years 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 9 Number of provisional determinations granted

	2018-19	2019-20
	July-June	
	Number (% of Total)	
Application type (proposed)		
A: New chemical entity/New biological entity/Fixed dose combination	4 (44%)	4 (40%)
C: Extension of indications	5 (56%)	6 (60%)
Total	9 (100%)	10 (100%)

Table 10 Provisional approval registrations

	2018-19		2019-20	
	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	2 (33%)	135	4 (40%)	199
C: Extension of indications	4 (67%)	62	6 (60%)	68
Total	6 (100%)	71	10 (100%)	135

2. Over-the-Counter Medicines

Over-the-counter 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 11 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'. - Implemented 1 July 2017	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 12 Median approval time for OTC medicine applications

	2018-19	2019-20
	July to June	
New medicine applications (days)		
N1	30	20
N2	48	0.5
N3	95	104
N4	97	159
N5	121	113
Change applications (days)		
C1	4.5	6.5
C2	36	29
C3	84	N/A
C4	109	75

Table 13 OTC medicine approval time against target time by application category for July 2019 to June 2020

Application type	Number completed (% of Total)	Range	Mean	Median	% within target
New medicines					
N1	75 (45%)	1-59	22	20	99
N2	6 (4%)	0-46	15	0.5	100
N3	52 (31%)	0-426	149	104	69
N4	19 (11%)	50-241	158	159	68
N5	15 (9%)	113-211	154	113	93
Total	167				
Change applications					
C1	229 (25%)	0-36	8	7	96
C2	685 (75%)	0-202	32	29	91
C3	0 (0%)	N/A	N/A	N/A	N/A
C4	1 (0.1%)	75	75	75	100
Total	916				

2.2. Applications

2.2.1 New OTC medicine applications

Table 14 Applications received for new OTC medicines and changes to existing medicines

	2018-19	2019-20
	July to June	
	Number (% of Total)	
New medicine applications		
N1	100 (40%)	96 (44%)
N2	18 (7%)	10 (5%)
N3	70 (28%)	64 (30%)
N4	39 (16%)	27 (13%)
N5	23 (9%)	19 (9%)
Total	250 (100%)	216 (100%)
Change applications		
CN	197 (18%)	157 (15%)
C1	197 (18%)	240 (23%)
C2	675 (62%)	615 (60%)
C3	7 (0.6%)	7 (0.7%)
C4	6 (0.6%)	7 (0.7%)
Total	1082 (100%)	1026 (100%)

2.2.2 Completed applications

Table 15 New OTC medicine applications completed and outcomes

	2018-19	2019-20
	July to June	
	Number (% of Total)	
N1		
Approved	129 (98%)	75 (96%)
Rejected	0	0
Withdrawn by sponsor	3 (2%)	3 (4%)
Returned/failed screening	0	0
Total	132 (100%)	78 (100%)
N2		
Approved	18 (82%)	6 (86%)
Rejected	0	0
Withdrawn by sponsor	4 (18%)	1 (14%)
Returned/failed screening	0	0
Total	22 (100%)	7 (100%)
N3		
Approved	52 (81%)	52 (93%)
Rejected	0	0
Withdrawn by sponsor	0	1 (2%)
Returned/failed screening	12 (19%)	3 (5%)
Total	64 (100%)	56 (100%)
N4		
Approved	13 (65%)	19 (86%)
Rejected	0	0
Withdrawn by sponsor	3 (15%)	0
Returned/failed screening	4 (20%)	3 (14%)
Total	20 (100%)	22 (100%)
N5		
Approved	9 (90%)	15 (79%)
Rejected	0	0
Withdrawn by sponsor	0	2 (11%)
Returned/failed screening	1 (10%)	2 (11%)
Total	10 (100%)	19 (100%)

Table 16 OTC change applications completed and outcomes

	2018-19	2019-20
	July to June	
	Number (% of Total)	
C1		
Approved	182 (97%)	229 (99%)
Rejected	0	0
Withdrawn by sponsor	6 (3%)	1 (0.4%)
Returned/failed screening	0	0
Total	188 (100%)	230 (100%)
C2		
Approved	549 (99%)	685 (99%)
Rejected	0	0
Withdrawn by sponsor	7 (1%)	5 (0.7%)
Returned/failed screening	0	0
Total	556 (100%)	690 (100%)
C3		
Approved	8 (80%)	0
Rejected	0	0
Withdrawn by sponsor	1 (10%)	4 (100%)
Returned/failed screening	1 (10%)	0
Total	10 (100%)	4 (100%)
C4		
Approved	2 (100%)	1 (100%)
Rejected	0	0
Withdrawn by sponsor	0	0
Returned/failed screening	0	0
Total	2 (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 17 Number of other OTC medicine applications

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Requests for advice for the purpose of listing a medicine as a pharmaceutical benefit		
B1	2 (100%)	0
B3	0	0
Total	2 (100%)	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	21 (95%)	7 (100%)
Rejected	1 (5%)	0
Total	22 (100%)	7 (100%)

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 18 Registered complementary medicine applications by outcome

	2018-19	2019-20
	July to June	
	Number (% of Total)	
New medicines		
Approved	5 (71%)	9 (56%)
Rejected	0	0
Withdrawn	2 (29%)	6 (38%)
Returned/failed screening	0	1 (6%)
Total	7 (100%)	16 (100%)
Variations		
Approved	18 (100%)	32 (97%)
Rejected	0	1 (3%)
Withdrawn	0	0
Returned/failed screening	0	0
Total variations completed	18 (100%)	33 (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	1 (100%)	1 (100%)
Rejected	0	0
Withdrawn	0	0
Total	1 (100%)	1 (100%)

4. 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 regulation. This includes assessment of evidence of efficacy and labelling. If we find the medicine does not comply with all applicable regulatory requirements, the medicine's listing may be suspended or cancelled.

4.1. New ingredients permitted for use in listed medicines

Table 19 New listed medicine ingredient applications by outcome

	2018-19	2019-20
	July to June	
Application outcome		
Approved	15 (88%)	9 (75%)
Rejected	1 (6%)	0
Withdrawn	1 (6%)	3 (25%)
Returned/failed screening	0	0
Total completed	17 (100%)	12 (100%)

4.2. Indications permitted for use in listed medicines

Table 20 Permitted indication applications by outcome

	2018-19	2019-20
	July to June	
Application outcome		
Approved	2 (18%)	3 (14%)
Rejected	5 (46%)	8 (36%)
Withdrawn	4 (36%)	11 (50%)
Total completed	11 (100%)	22 (100%)

4.3. Listed medicines

Table 21 New listed medicines

	2018-19	2019-20
	July to June	
New listed medicines	1893	2008

Table 22 Listed medicine variations under section 9D(1) of the Act

Subsection 9D(1) of the Act 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.

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Medicine variation		
Approved	131 (78%)	161 (88%)
Rejected	13 (8%)	4 (2%)
Withdrawn	24 (14%)	19 (10%)
Total	168 (100%)	184 (100%)

Table 23 Listed medicine applications under section 14/14A of the Therapeutic Goods Act 1989

Sections 14 and 14A of the Act provides for consent to be given in writing for the import, supply or export of therapeutic goods that do not comply with applicable standards. These applications are considered by a Delegate.

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Application		
Exemption granted[a]	11 (85%)	15 (63%)
Rejected	0	5 (21%)
Withdrawn	2 (15%)	4 (16%)
Total	13 (100%)	24 (100%)

[a] Sponsors can apply for certain exemptions under section 14 and 14A of the *Therapeutic Goods Act 1989*. Applications seek consent to import, export or supply a listed medicine that does not comply with the applicable standards.

4.3.1 Investigations

Investigations arise from notifications, complaints and referrals from internal and external stakeholders and screening of recently listed medicines on the ARTG, but can also include products not listed on the ARTG. All investigations are prioritised based on a risk management approach to provide the perceived greatest overall benefit for the Australian public. Investigations may be completed with a number of actions, such as initiating a targeted review or referral to another area of the TGA.

Table 24 Listed medicine investigations and actions undertaken

	2018-19	2019-20
	July to June	
	Number (% of total)	
Initiated investigations	81	130[d]
Completed investigations[a]	36	83[d]
Initiated compliance review(s)	20 (55%)	28 (34%)
Issued warning or educational letter	1 (3%)	9 (11%)
Advice provided to complainant	0 (0%)	4 (5%)
Referred to another TGA area or government organisation	1 (3%)	28 (34%)
No further action taken[b]	14 (39%)	14 (16%)
Total actions undertaken[c]	36 (100%)	83 (100%)

[a] Investigations with ensuing actions completed.

[b] The outcome 'no further action taken' includes examples where the investigation was resolved by other means such as the product has been or is currently under review; or the complaint was not justified and did not warrant further action.

[c] An investigation may give rise to more than 1 action.

[d] Assessments of goods at the food-and-cosmetic-medicine interfaces are included in the numbers of initiated and completed investigations for FY 2019-20. These assessments were not previously reported on.

4.3.2 Compliance reviews

Listed medicines are not individually evaluated by the TGA before they are included on the ARTG. However, a proportion are reviewed post-market to check their compliance against relevant regulatory requirements. Compliance reviews may only review selected listing requirements.

Medicines may be randomly selected or targeted for a review. Medicines are randomly selected for review by a computer, based on a mathematical model. Targeted reviews can originate from a number of signals and are initiated following an investigation.

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.

Since November 2019, the TGA has published results of listed medicine compliance reviews on the TGA website.

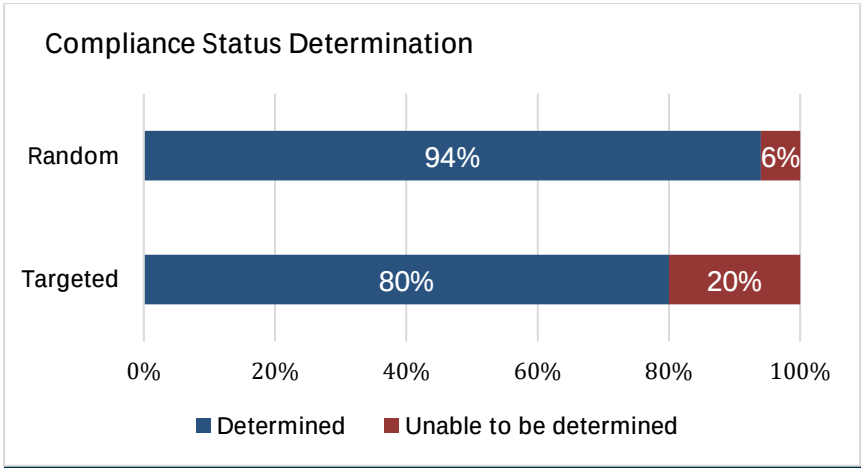
Table 25 Listed medicine reviews by type

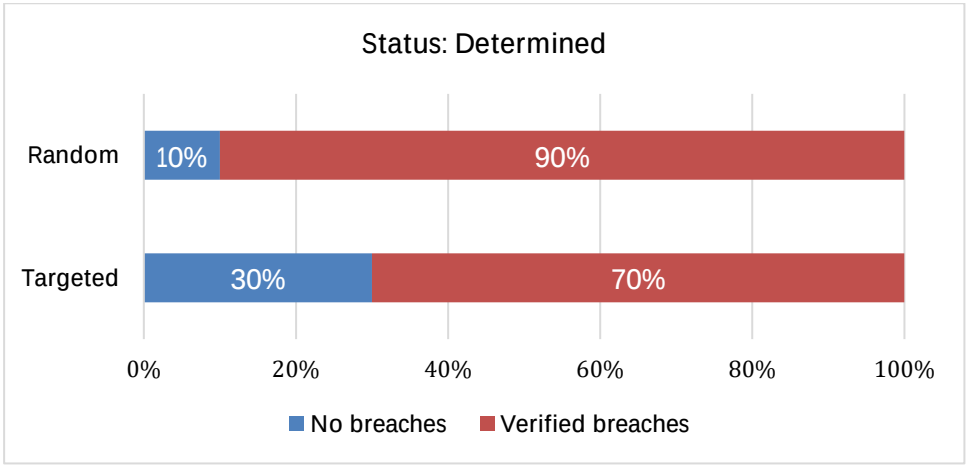
	2018-19	2019-20
	July to June	
	Number (% of Total)	
Initiated reviews		
Targeted reviews	127 (91%)	163 (95%)
Random reviews	12 (9%)	9 (5%)
Total	139 (100%)	172 (100%)
Reviews on hand	131	111
Completed reviews		
Targeted reviews	99 (55%)	162 (83%)
Random reviews	82 (45%)	33 (17%)
Total	181 (100%)	195 (100%)

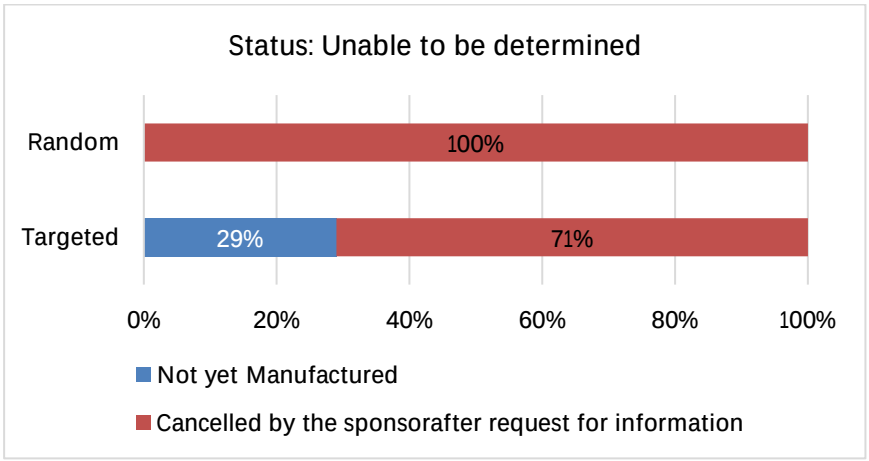
Table 26 Completed listed medicine reviews by outcome

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Compliance status determined		
Medicines with no compliance breaches	38 (27%)	42 (26%)
Medicines with verified compliance breaches	102 (73%)	118 (74%)
Sub-total	140 (100%) **(77%)**	160 (100%) **(82%)**
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	30 (73%)	26 (74%)
Medicines not yet manufactured	11 (27%)	9 (26%)
Sub-total	41 (100%) **(23%)**	35 (100%) **(18%)**
Product not a therapeutic good	0 **(0%)**	0 **(0%)**
Total completed	181 **(100%)**	195 **(100%)**

Figure 3 Outcomes of compliance reviews by reason for initiation[a]







[a] In this period, of the medicines for which we were able to determine a compliance status, 89% had verified compliance breaches when initiated by random selection, which is consistent with the non-compliance rate from the previous period (88%). For medicines that were targeted for review and the compliance status was determined, a markedly lower percentage (57%) were found to have compliance breaches; this was attributable to a significant number targeted of reviews to specifically check compliance with a requirement for label warning statements, for which many medicines were compliant.

Table 27 Types of listed medicine compliance issues identified

Of the completed compliance reviews, the following are the types of issues identified in those medicines where a compliance breach was verified. Individual medicines may have multiple issues identified.

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Type of compliance issue		
Information provided in ARTG entry[a]	30 (12%)	32 (14%)
Manufacturing, quality and/or formulation	15 (6%)	8 (4%)
Labelling	49 (20%)	68 (30%)
Advertising	40 (16%)	42 (19%)
Unacceptable presentation[b]	52 (21%)	35 (16%)
Evidence[c]	51 (21%)	21 (9%)
Safety[d]	1 (0.4%)	0 (0%)
Non-response to a request for information[e]	2 (1%)	3 (1%)
Other[f]	4 (2%)	16 (7%)
Total	244 (100%)	225 (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.

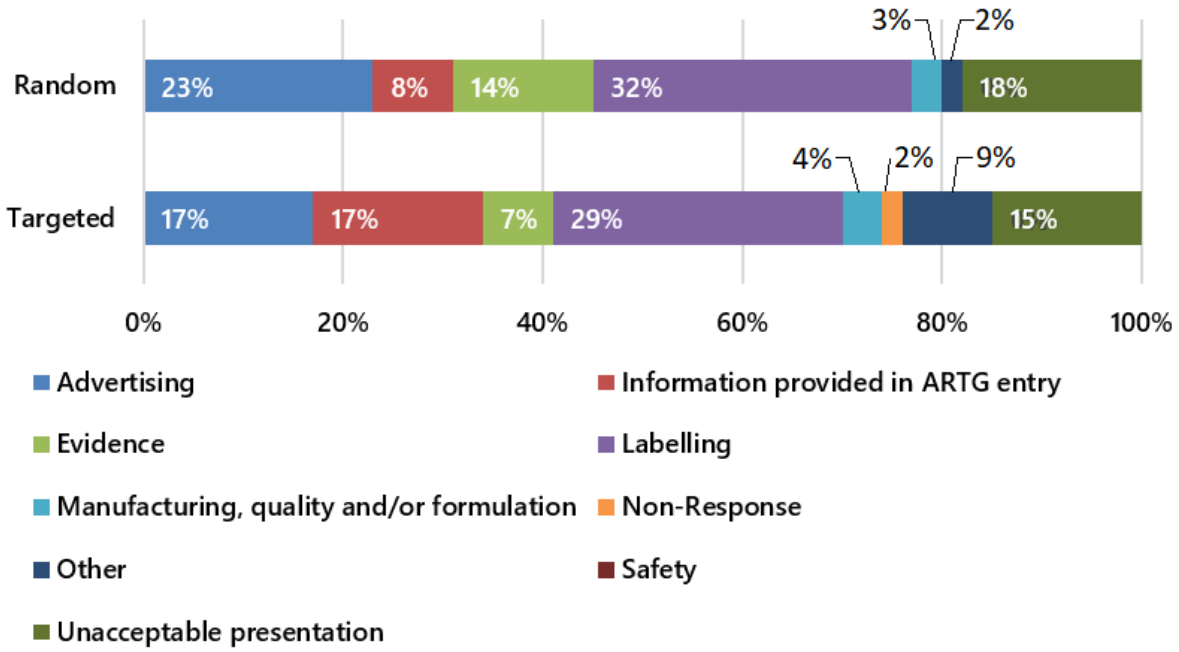
[c] 'Evidence' means the evidence held by the sponsor does not support the claims relating to the medicine.

[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.

Figure 4[a] Types of compliance issues identified by reason for initiation



[a] Reviews are either randomly selected or targeted for a particular issue. Multiple breaches may be identified for each medicine that is found to be non-compliant; for example, 74% of all randomly-selected non-compliant medicines were found to have issues related to the labelling of the medicine, yet this breach accounted for 32% of the total breaches identified across all randomly-selected non-compliant medicines. These figures are not corrected for the nature of information assessed during a review. For example, of those randomly-selected non-compliant medicines for which Labelling was assessed, 87% were found to have a 'Labelling' breach.

Table 28 Actions taken following listed medicine reviews

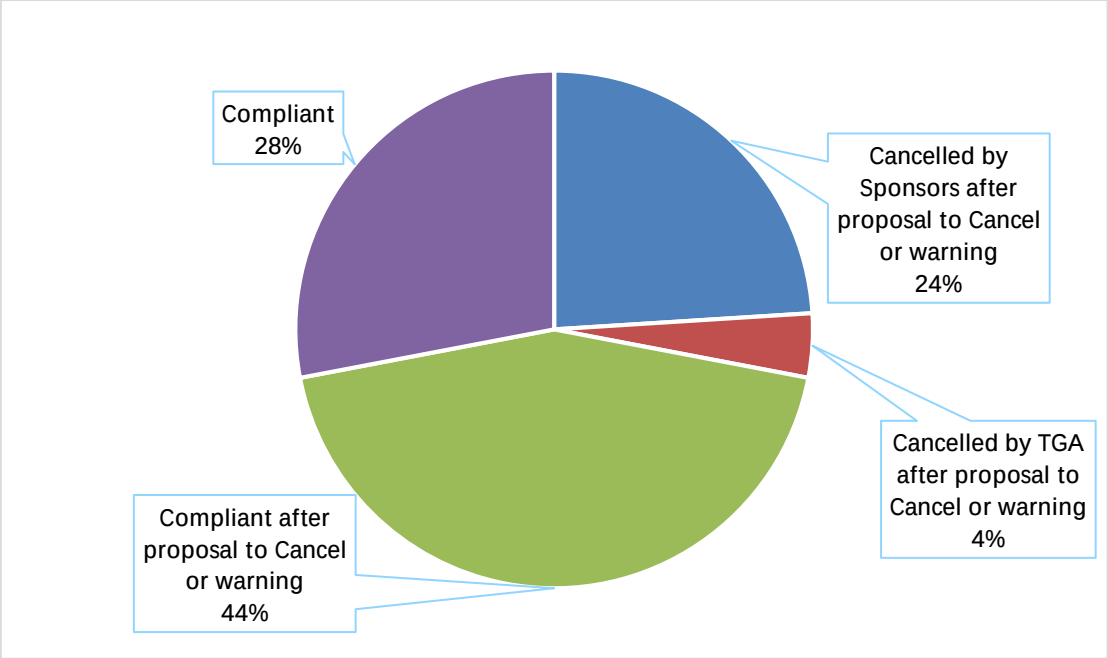
	2018-19	2019-20
	July to June	
	Number (% of Total)	
Actions following a Request for Information		
Medicines found to be compliant and review concluded	38 (27%)	41 (26%)
Medicines cancelled by the TGA without a proposal to cancel notice	0	0 (0%)
Proposal to cancel notice or warning[a] sent by the TGA	102 (73%)	119 (74%)
Total	**140 (100%)**	**160 (100%)**
Actions following Proposal to Cancel notice[b] by outcome		
Medicines no longer on the ARTG	32 (100%) **(31%)**	45 (100%) **(38%)**
Cancelled by the TGA	3 (9%)	7 (16%)
Cancelled by sponsors after being notified of compliance breaches	29 (91%)	38 (84%)
Medicines remaining on the ARTG	70 (100%) **(69%)**	71 (100%) **(60%)**
Reviews concluded after compliance breaches were addressed	70 (100%)	59 (83%)
Reviews concluded after sponsor reminded of their obligations	0 (0%)	11 (15%)
No further action required	0 (0%)	1 (2%)
Other[c]	0	3 (100%) **(2%)**
Total	**102 (100%)**	**119 (100%)**

[a] In some targeted review projects, sponsors are sent a 'warning' letter instead of a 'proposal to cancel' letter. A proposal to cancel or warning letter is considered the same for reporting purposes.

[b] The figures provided under 'Actions following a Proposal to Cancel notice by outcome' are a breakdown of the corresponding figures provided for the same under 'Actions following a Request for Information'.

[c] Includes reviews of medicines that are exempt from inclusion in the ARTG.

Figure 5[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. There was a slight decrease in the number of listed medicines cancelled by the TGA following a Proposal to Cancel or warning letter (2%) compared with the previous period (5%).

5. Biologicals and Blood Components

5.1. Inclusion of biologicals

Table 29 Applications for biologicals[a] received and on hand

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Applications received		
Technical Master File (TMF)[b] new	0	0
TMF annual updates	3 (4%)	4 (5%)
TMF variations	18 (23%)	20 (27%)
TMF notifications	12 (16%)	10 (14%)
Plasma Master File[c] annual updates	12 (16%)	9 (12%)
Biological Class 2 – new applications	1 (1%)	0
Biological Class 3 – new applications	0	0
Biological Class 4 – new applications	1 (1%)	1 (1%)
Biological Class 2 – variations	23 (30%)	16 (22%)
Biological Class 3 – variations	3 (4%)	5 (7%)
Biological Class 4 – variations	4 (6%)	9 (12%)
Total received	77 (100%)	74 (100%)
Applications on hand		
TMF new	0	0
TMF annual updates	1 (7%)	3 (18%)
TMF variations	5 (33%)	7 (41%)
TMF notifications	0	1 (6%)
Plasma Master File annual updates	4 (27%)	2 (12%)
Biological Class 2 – new applications	1 (7%)	1 (6%)
Biological Class 3 – new applications	1 (7%)	1 (6%)
Biological Class 4 – new applications	1 (7%)	1 (6%)
Biological Class 2 – variations	2 (13%)	0
Biological Class 3 – variations	0	0
Biological Class 4 – variations	0	1 (6%)
Total on hand	15 (100%)	17 (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 30 Completed applications for biologicals

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Biologicals applications		
Technical Master File (TMF) new	0	0
TMF annual updates	3 (4%)	2 (3%)
TMF variations	13 (19%)	15 (22%)
TMF notifications	12 (17%)	9 (13%)
Plasma Master File annual updates	9 (13%)	11 (16%)
Biological Class 2 – new applications	2 (3%)	0
Biological Class 3 – new applications	0	0
Biological Class 4 – new applications	1 (1%)	1 (1%)
Biological Class 2 – variations	23 (33%)	18 (26%)
Biological Class 3 – variations	3 (4%)	4 (6%)
Biological Class 4 – variations	4 (6%)	9 (13%)
Total completed	70 (100%)	69 (100%)

6. Medicine and Vaccine Adverse Event Reports

6.1. Adverse medicine and vaccine reaction notifications

Table 31 Source of notifications of medicine and vaccine adverse reactions[a]

	2018-19	2019-20
	July to June	
Accepted cases total	22467	23476
Reports by health professionals	4415	4744
Patients/consumers	704	904
Pharmaceutical companies	13874	14418
Other source	3474	3410
Rejected/withdrawn cases	1550	1422
Total received	24017	24,898
Mean number of reports received weekly	462	479
Vaccine reports included in this table	4225	4103

[a] Data is subject to change due to receipt of further information related to individual reports resulting in their amendment, or further case processing.

7. Medical Devices

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

- **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.
- **Priority review of medical devices**: A new pathway has been developed to allow faster processing of applications for devices that meet certain criteria for novelty and health benefits.
- **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.

7.1. Conformity assessment

7.1.1 Applications

Table 32 Number of conformity assessment applications (medical devices including IVDs)

	2018-19	2019-20
	July to June	
Conformity assessment applications		
Applications received	279	308
Applications on hand	252	222
Applications completed (including withdrawn or lapsed applications).	273	342

7.1.2 Outcomes

Table 33[a] Outcomes of conformity assessment applications

	2018-19	2019-20
	July to June	
New		
Approved	63	54
Rejected	0	0
Withdrawn/ Lapsed	17	39
Variation (changes and re-certifications)		
Approved	169	228
Rejected	0	0
Withdrawn/ Lapsed	24	21

[a] The table has been broken down into 'New' and 'Variation' assessment application to provide additional transparency.

7.1.3 Processing timeframes

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

Table 34 TGA processing times for new devices and variations

	2018-19	2019-20
	July to June	
New devices		
Mean TGA processing time (days)	160	129
Median TGA processing time (days)	196	158
Variations (changes and recertifications)		
Mean TGA processing time (days)	114	137
Median TGA processing time (days)	97	144

7.2. Inclusion of medical devices (including IVDs)

7.2.1 Applications

Table 35 Applications for inclusion – medical devices (including IVDs)

	2018-19	2019-20
	July to June	
Class I medical devices[a]		
Applications received	1545	3992
Applications completed	1631	3998
Class I measuring medical devices		
Applications received	46	73
Applications completed	46	74
Applications on hand[b]	0	0
Class I sterile medical devices		
Applications received	198	273
Applications completed	207	271
Applications on hand[b]	1	3
Class IIa medical devices		
Applications received	1186	1384
Applications completed	1191	1376
Applications on hand[b]	27	24
Class IIb medical devices		
Applications received	581	685
Applications completed	589	681
Applications on hand[b]	50	41
Class III medical devices		
Applications received	476	298
Applications completed	404	249
Applications on hand[b]	194	254
Class III Joint Reclassification medical devices		
Applications received	0	0
Applications completed	6	0
Applications on hand[b]	0	0

	2018-19	2019-20
	July to June	
Active Implantable Medical Devices (AIMD)		
Applications received	37	55
Applications completed	28	34
Applications on hand[b]	18	40
Class 1 IVDs[c]		
Applications received	72	114
Applications completed	72	112
Applications on hand[b]	1	3
Class 2 IVDs		
Applications received	67	64
Applications completed	71	60
Applications on hand[b]	7	11
Class 3 IVDs		
Applications received	53	126
Applications completed	43	105
Applications on hand[b]	20	29
Class 4 IVDs		
Applications received	30	13
Applications completed	30	13
Applications on hand[b]	0	0

[a] Class I medical devices are automatically included (i.e. these applications are completed within 24 hours). There are no applications for this classification of device 'on hand'. Differences in the number received and finalised relate to those applications received on the last day of the reporting period and/or data migration processes.

[b] Applications on hand – figures shown are correct as of the date when the data was extracted. There may also be delays between the date of the decision and the time when the system is updated due to administrative and/or data migration processes.

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

7.2.2 Outcomes

Class I automatically included medical devices are not counted in the outcomes for inclusion applications as these applications cannot be rejected.

Table 36 Outcomes of medical device applications by classification

	2018-19				2019-20			
	July to June							
	Number (% of Total)							
Device Classification	Approved/ Accepted	Rejected/ Lapsed	Withdrawn	Total of applications by classification	Approved/ Accepted	Rejected/ Lapsed	Withdrawn	Total of applications by classification
Class I	1691 (40%)	0	0	1691 (39%)	3998 (57%)	0	0	3998 (57%)
Class I Measurement	45 (1%)	0	1 (0.6%)	46 (1%)	74 (1%)	0	0	74 (1%)
Class I Sterile	193 (5%)	0	14 (9%)	207 (5%)	271 (4%)	0	0	271 (4%)
Class IIa	1148 (27%)	3 (17%)	42 (26%)	1191 (27%)	1375 (20%)	0	1 (▼0.1%)	1376 (20%)
Class IIb	535 (13%)	3 (17%)	51 (31%)	589 (14%)	679 (10%)	0	2 (▼0.1%)	681 (10%)
Class III	362 (9%)	6 (35%)	36 (22%)	404 (9%)	249 (4%)	0	0	249 (4%)
Class III Reclassification	5 (0.1%)	0	1 (0.6%)	6 (0.1%)	0	0	0	0
AIMD	28 (1%)	0	0	28 (0.6%)	34 (0.5%)	0	0	34 (0.5%)
Class 1 IVD	71 (2%)	1 (56%)	0	72 (2%)	112 (2%)	0	0	112 (2%)
Class 2 IVD	60 (1%)	1 (6%)	10 (6%)	71 (2%)	60 (1%)	0	0	60 (0.8%)
Class 3 IVD	32 (1%)	3 (18%)	8 (5%)	43 (1%)	103 (2%)	0	2 (▼0.1%)	105 (1%)
Class 4 IVD	30 (1%)	0	0	30 (0.7%)	13 (0.2%)	0	0	13 (0.2%)
Total of all applications by status	4185 (96%)	17 (0.4%)	163 (4%)	4378 (100%)	6968 (99.9%)	0	5 (0.1%)	6973 (100%)

7.2.3 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 work days and for Level 2 application audits is 60 TGA work days (reflected in 'TGA days').

Table 37 Processing times for medical device application audits (including IVDs)

	2018-19			2019-20		
	Number of applications (% of Total)	Sponsor days	TGA days[a]	Number of applications (% of Total)	Sponsor days[b, d]	TGA days[a, d]
Mean Processing Time						
Medical devices						
Applications completed without audit	1850 (76%)			2330 (87%)		
Non-compulsory audit[c]	201 (8%)	44	99	89 (3%)	52	82
Level 1 compulsory audit	156 (6%)	37	24	47 (2%)	44	55
Level 2 compulsory audit	236 (10%)	63	99	212 (8%)	74	115
Total	2443 (100%)			2678 (100)		
IVDs						
Applications completed without audit	86 (59%)			119 (61%)		
IVD non-compulsory audit	8 (5%)	18	36	13 (7%)	18	36
IVD compulsory audit	53 (36%)	82	94	64 (33%)	19	19
Total	147 (100%)			196 (100)		

[a] TGA time starts when the application is selected for audit, is based on working days, and excludes the time when we wait for information or payment from the sponsor.

[b] Days taken for sponsor to provide further information/pay fees etc.

[c] Non-compulsory audit – estimate for the audit processing time does not include applications for reclassification of joint replacement medical devices received during transitional period (Class III Joint Reclassification medical devices).

[d] Due to technical and data migration issues the timeframes calculated for this reporting period may have some minor inaccuracies.

[e] *Statistics for the group set of TGA/Sponsor days unavailable for IVD non-compulsory audit - numbers taken from last year.

Table 37 Processing times for medical device application audits (including IVDs) [cont]

	2018-19			2019-20		
	Number of applications (% of Total)	Sponsor days	TGA days[a]	Number of applications (% of Total)	Sponsor days[b, d]	TGA days[a, d]
Median Processing Time						
Medical devices						
Applications completed without audit	1850 (76%)			2330 (87%)		
Non-compulsory audit[c]	201 (8%)	29	56	89 (3%)	39	45
Level 1 compulsory audit	156 (6%)	31	15	47 (2%)	34	26
Level 2 compulsory audit	236 (10%)	50	85	212 (8%)	63	98
Total	2443 (100%)			2678 (100)		
IVDs						
Applications completed without audit	86 (59%)			119 (61%)		
IVD non-compulsory audit	8 (5%)	19	25	13 (7%)	19	25
IVD compulsory audit	53 (36%)	66	84	64 (33%)	2	8
Total	147 (100%)			196 (100)		

[a] TGA time starts when the application is selected for audit, is based on working days, and excludes the time when we wait for information or payment from the sponsor.

[b] Days taken for sponsor to provide further information/pay fees etc.

[c] Non-compulsory audit – estimate for the audit processing time does not include applications for reclassification of joint replacement medical devices received during transitional period (Class III Joint Reclassification medical devices).

[d] Due to technical and data migration issues the timeframes calculated for this reporting period may have some minor inaccuracies.

[e] *Statistics for the group set of TGA/Sponsor days unavailable for IVD non-compulsory audit - numbers taken from last year.

Table 38 Number of priority review determinations[a] granted

	2018-19	2019-20
	July-June	
Application type (proposed)		
A: Conformity Assessment (priority applicant) determinations	1	5
B: Medical Devices (priority applicant) determinations	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. Designation decisions lapse after six (6) months, unless an application for either TGA conformity assessment or ARTG inclusion is received during this time.

Table 39 Number of medical devices approved through the priority review pathway

	2019-20	
	July-June	
Application Type	Number Approved (% of Total)	Median approval time (TGA working days)
A: Conformity Assessment	4 (100%)	70
B: Medical Devices (ARTG inclusion)	N/A	N/A
Total	4 (100%)	70

7.3. Post-market monitoring

7.3.1 Compliance reviews

As Class I medical devices are included on the ARTG following a self-certification being made online by the sponsor through a computer-generated decision process, we undertake post-market compliance reviews for these devices. This previously included restricted word reviews (up until January 2020), where potentially inappropriate Class I device inclusions are identified by the use of specific words indicative of risk, or listing issues relating to the inclusion of the device. Our current practice is to assess all new Class I ARTG inclusions and request information where there may be uncertainty regarding the appropriateness of the inclusion.

We also conduct targeted compliance reviews that are initiated on a case by case basis. These may be conducted in relation to devices of any Class.

Table 40 Class 1 medical device reviews

	2018-19	2019-20
	July to June	
Restricted word reviews		
Reviews completed	40	388
Reviews commenced	40	413
Reviews on hand	0	25
Targeted compliance reviews[a]		
Reviews completed	235	87
Reviews commenced	250	145
Reviews on hand	15	58
Total inclusions assessed	N/A[b]	3892

[a] The number of targeted reviews includes the number of compliance reviews undertaken in relation to all classes of medical devices.

[b] Figure was unavailable in 2018-19

7.3.2 Post-market reviews

Table 41 Medical device targeted reviews

	2018-19	2019-20
	July to June	
Post market reviews		
Reviews commenced – number of ARTG entries	545	1315
Reviews completed – number of ARTG entries	285	435
Reviews on hand – number of ARTG entries	677	1557

7.3.3 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 42 Number of medical device incident reports and processing times

	2018-19	2019-20
	July to June	
Device incident reports		
Reports received	5874	6230
Reports completed	5654	5944
Reports still in progress	239	162
Processing time		
Mean TGA processing time (days)	14	17
Median TGA processing time (days)	9	▼1
Percentage processed within target timeframe	94%	93%

Table 43 Medical device incident report outcomes[a]

	2018-19	2019-20
	July to June	
Incident report outcome		
Reviewed and used for trend analysis purposes	5129	5354
Reviewed, no further action required	280	448
Product recall	55	21
Recall for product correction	72	20
Hazard alert	68	20
Product notification	0	3
Safety alert	22	5
Product enhancement/improvement notice	8	1
Instructions for use amended	8	4
Referral for post-market review	94	101
Refer to another TGA Branch[b]	24	18
Company warned	3	3
Product suspended from ARTG	4	0
Product cancelled from ARTG	16	34
Manufacturing process improvements	71	16
Quality system process improvements	3	1
Maintenance carried out by the hospital	1	1
Change to design	15	4
Not device related	2	5
Other	47	175

[a] Outcomes are not mutually exclusive.

[b] The Incident report (DIR) may be referred onto another section for their action. These areas include but are not limited to Recalls, Regulatory Compliance, Clinical Trials and Advertising. Generally these reports are closed off in the DVM database unless there is more than one issue noted within the report. It may also still be investigated by DVM depending on this issue.

7.3.4 Devices manufacturing

Table 44 Outcomes of Quality Management System (QMS) audits of Australian manufacturers

Note: The ability to conduct audits - both domestic and overseas – between January to June 2020 was severely impacted by travel restrictions aimed at controlling the spread of the COVID-19 virus.

	2018-19	2019-20
	July to June	
QMS audits (Australia)		
Number of audits conducted	35	21
Satisfactory compliance (of completed audits)	93%	100%
Marginal compliance (of completed audits)	7%	0%
Unacceptable (of completed audits)	0%	0%
Close-out in Progress	23%	62%
Processing time		
Initial audits conducted within 3 months of application	25%	20%
Re-audits conducted within 6 months of due date	57%	13%

Table 45 Outcomes of QMS audits of overseas manufacturers

	2018-19	2019-20
	July to June	
QMS audits (overseas)		
Number of audits conducted	34	15
Satisfactory compliance (of completed audits)	100%	0%
Marginal compliance (of completed audits)	0%	0%
Unacceptable (of completed audits)	0%	0%
Close-out in Progress	38%	40%
Processing time		
Initial certification audits conducted within 6 months of application	48%	55%
Certification re-audits conducted within 6 months of due date	15%	50%

Table 46 Outcomes of MDSAP

	2018-19	2019-20
	July to June	
MDSAP Assessments (overseas)		
Number of auditing organisation assessments	3	3
Number of witnessed manufacturing audits	5	6

8. Listed Other Therapeutic Goods (Disinfectants)

Following regulatory amendments to disinfectants in 2018, disinfectants that includes claims (including virucidal claims) have been downregulated from registered products to listed products. As per the current Regulations, 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.

8.1. Disinfectants

8.1.1 Applications

Table 47 Applications for listing – listed OTG

	2019-20
	July to June
Listed OTG (Disinfectants)	
Applications received	83
Applications completed	33
Applications on hand[a]	66

[a] Applications on hand – figures shown are correct as of the date when the data was extracted. There may be delays between the date of the decision and the time when the system is updated due to administrative and/or data migration processes.

Table 48 Outcomes of listed OTG applications[a]

	2019-20			
	July to June			
	Number (% of Total)			
	Approved/ Accepted	Rejected/ Lapsed	Withdrawn	Total of applications
Listed OTG (Disinfectants)	33	0	0	33 (100%)

[a] The reporting period 2019-2020 now includes new data sets in relation to listed OTGs.

9. Exports

9.1. Export only medicines

The TGA is in the process of updating information on the website for the export of therapeutic goods from Australia, with a new webpage to be published in the second half of 2020. The updated webpage will provide clear and concise information regarding the export of therapeutic goods from Australia, and will be user-focused to ensure that finding required information is easy and streamlined.

Table 46 Number of approved applications for export-only medicines and export certifications and relevant processing time for July 2019 to June 2020

	Total approved 2019-20	Target processing time (days)	2018-19	2019-20
			Average processing time (days)	
Export-only medicines				
New applications	165	30	16	16
Variation and grouping applications	106	30	15	16
Export certification				
Medicines	1501	15	11	10
Medical devices	362	10	4	4

The TGA issues permits for the export of human substances under regulation 8 of the *Customs (Prohibited Exports) Regulations 1958*. 'Human substances' refers to goods of human origin which include human body fluids, organs and other tissues or substances derived from human blood.

The online application form has been very successful since its introduction in August of 2019 and has allowed Australians who require a permit for human substances to interact with the TGA directly.

10. Access to Unapproved Therapeutic Goods

10.1. 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, three 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 except for drugs of abuse in Schedule 9 of the Poisons Standard (where the manufacture, possession, sale or use is prohibited by state or territory law) which cannot be accessed through the SAS Category A process.

Table 47 SAS medicine notifications and applications

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	39,911[a] **(47%)**	40,069 **(35%)**
Category B applications		
Approved	18388 (88%)	58,735 (97%)
Cancelled	168 (0.8%)	39 (0%)
Withdrawn	802 (4%)	501 (1%)
Rejected	1 (0%)	0 (0%)
Pending at end of reporting period[b]	1464 (7%)	1,014 (2%)
Total Category B applications	20823 (100%) **(24%)**	60,289 **(53%)**
Category C notifications		
Total Category C notifications	24505 **(29%)**	13,956[c] **(12%)**
Total SAS notifications/applications received (all categories)	85239 **(100%)**	114,314 **(100%)**

[a] Due to system technical issues, the number of notifications received during some of this reporting period has been estimated.

[b] Pending applications are waiting on additional information to be supplied by the applicant.

[c] Due to an administrative backlog, SAS C notifications figures are correct as at October 2019

Table 48 SAS device notifications and applications

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	5117[a] **(60%)**	4,113 **(50%)**
Category B applications		
Approved	1,953 (90%)	3,218 (94%)
Cancelled	24 (1%)	7 (0%)
Withdrawn	51 (2%)	43 (1%)
Rejected	13 (0.6%)	66 (2%)
Pending at end of reporting period[b]	142 (7%)	120 (4%)
Total Category B applications	2,183 (100%) **(25%)**	3,454 (100%) **(42%)**
Category C notifications		
Total Category C notifications	1394 **(16%)**	699 [c] **(8%)**
Total SAS notifications/applications received (all categories)	8,694 **(100%)**	8,266 **(100%)**

[a] Due to system technical issues, the number of notifications receive during some of this report period has been estimated.

[b] Pending applications are waiting on additional information to be supplied by the applicant.

[c] Due to an administrative backlog, SAS C notifications figures are correct as at October 2019

Table 49 SAS biological notifications and applications

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Category A notifications		
Total Category A notifications	89[a] **(4%)**	89 **(7%)**
Category B applications		
Approved	1350 (92%)	955 (92%)
Cancelled	15 (1%)	0 (0%)
Withdrawn	55 (4%)	25 (3%)
Rejected	26 (2%)	0 (0%)
Pending at end of reporting period[b]	30 (2%)	56 (6%)
Total Category B applications	1476 (100%) **(66%)**	1,036 (100%) **(75%)**
Category C notifications		
Total Category C notifications	688 **(31%)**	256[c] **(19%)**
Total SAS notifications/applications received (all categories)	2253 **(100%)**	1381 **(100%)**

[a] Due to system technical issues, the number of notifications receive during some of this reporting period has been estimated.

[b] Pending applications are waiting on additional information to be supplied by the applicant.

[c] Due to an administrative backlog, SAS C notifications figures are correct as at October 2019

10.2. 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 three types of goods.

Table 50 Number of notifications for new clinical trials involving unapproved therapeutic goods received by therapeutic good type

	2018-19[b]	2019-20
	July to June	
	Number (% of Total)	
Therapeutic good type		
Medicine	466 (44%)	409 (42%)
Device[a]	173 (16%)	168 (17%)
Biological	13 (1%)	11 (1%)
Medicine and device	391 (37%)	384 (39%)
Device and biological	4 (0.4%)	7 (1%)
Medicine and biological	4 (0.4%)	3 (0.3%)
Medicine, device and biological	8 (0.8%)	2 (0.2%)
Total	1059 (100%)	984 (100%)

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

[b] Due to system technical issues, the number of notifications received during some of this reporting period has been estimated.

Table 51 Number of new clinical trial notifications involving unapproved therapeutic goods received by phase

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Clinical trial type		
Phase 1	285 (27%)	297 (30%)
Phase 2	264 (25%)	212 (22%)
Phase 3	260 (25%)	235 (24%)
Phase 4	82 (8%)	58 (6%)
Device	147 (14%)	169 (17%)
Bioavailability/equivalence	21 (2%)	13 (1%)
Total	1059 (100%)	984 (100%)

Table 52 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

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Therapeutic good type		
Medicine	1201 (38%)	1085 (34%)
Device[a]	287 (9%)	272 (8%)
Biological	19 (0.6%)	19 (0.5%)
Medicine and device	1643 (52%)	1803 (56%)
Device and biological	9 (0.3%)	23 (1%)
Medicine and biological	10 (0.3%)	8 (0.2%)
Medicine, device and biological	16 (0.5%)	15 (0.5%)
Total	3185 (100%)	3225 (100%)

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

The online system captures the actual number of notifications received for new clinical trials and requests to change significant details to clinical trials already notified. 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 53 Number of new clinical trials and variations[a] to previously notified clinical trials involving unapproved therapeutic goods received by phase

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Phases		
Phase 1	687 (22%)	832 (26%)
Phase 2	921 (29%)	788 (25%)
Phase 3	1196 (37%)	1209 (37%)
Phase 4	123 (4%)	122 (4%)
Device	227 (7%)	256 (8%)
Bioavailability/equivalence	31 (1%)	18 (0.5%)
Total	3185 (100%)	3225 (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.

10.3. 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. If a medical practitioner becomes an Authorised Prescriber they may prescribe the product to patients in their immediate care, within the indication specified, without seeking further approval from the TGA.

Table 54 Authorised Prescriber approvals for medicines, medical devices and biologicals

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Approvals by therapeutic good type		
Number of approvals for medicines	694 (57%)	1071 (74%)
Number of approvals for medical devices	527 (43%)	383 (26%)
Number of approvals for biologicals	1 (0.1%)	0 (0%)
Total	1222 (100%)	1454 (100%)

10.4. Section 19A approvals

Section 19A of the Therapeutic Goods Act provides the legislative basis for the Secretary of the Department of Health (the Secretary) 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.

	2018-19	2019-20
	July-June	
Applications processed		
New	52	84
Renewals	47	67
Total	99	151

11. Medicines and Biologicals Manufacturing

11.1. Manufacturing licences issued to Australian manufacturers

Table 55 Status of manufacturing licence applications

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Licence status (Australia) [a]		
New licences granted	15 (47%)	23 (30%)
Withdrawn application [b]	1 (3%)	45 (55%)
Revoked licences – at request of licence holder	13 (41%)	10 (12%)
Revoked licences – TGA	0	0
Suspended – at request of licence holder	3 (9%)	3 (3%)
Suspended – TGA	0	0
Total	32 (100%)	81 (100%)

[a] As at 30 June 2019, there were 254 Australian companies holding manufacturing licences covering 396 sites.
[b] In previous financial years the number of new applications withdrawn at applicant request were reported. The method of calculation has changed this year to include all applications withdrawn at the applicant's request.

Table 56 Outcomes of inspections of Australian manufacturers

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Compliance status (Australia)		
Number of inspections conducted	195	163
Satisfactory compliance (of completed inspections)	152 (78%)	99 (60%)
Marginal compliance (of completed inspections)	29 (15%)	32 (20%)
Unacceptable (of completed inspections)	8 (4%)	5 (3%)
Compliance under assessment at period end	6 (3%)	27 (17%)
Processing time		
Initial inspections conducted within 3 months of application	16 (94%)	12 of 17 (71%) [a]
Re-inspections conducted within 6 months of due date	112 (75%)	82 of 117 (70%)[b]

a. There were a total of five domestic initial inspections which did not achieve the three month processing timeframe. Four of these were delayed at the request of the manufacturer, as they were not ready for inspection. The remaining inspection was delayed, due to inspector availability.

b. There were a total of thirty five domestic re-inspections which did not achieve the six month processing timeframe. The majority of the inspections (23 of the 35 delayed inspections) were blood and biological manufacturers, delayed due to insufficient inspector resources.

11.2. Approval (certification) of overseas manufacturers

Table 57 Manufacturing certification application by status (overseas)

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Applications (overseas) [a]		
New applications received [b]	36 (46%)	22 (22%)
Re-inspection applications [b]	42 (54%)	76 (78%)
Total applications	78 (100%)	98 (100%)
Applications completed		
Certified	83 (56%)	86 (54%)
Rejected [c]	66 (44%)	72 (46%)
Total completed	149 (100%)	158 (100%)

[a] As at 30 June 2020, there were 187 overseas manufacturers covering 222 manufacturing sites that are subject to TGA inspection.

[b] Refers to applications that generated an inspection, undertaken by the TGA. However, this does not correlate with completed applications, as the certification process may be continuing across financial years.

[c] Rejections include withdrawn applications.

Table 58 Outcomes of inspections of overseas manufacturers

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Inspection status (overseas)		
Number of inspections conducted	75	51[a]
Satisfactory compliance (of completed inspections)	64 (85%)	31 (61%)
Marginal compliance (of completed inspections)	11 (15%)	13 (25%)
Unacceptable (of completed inspections)	0 (0%)	3 (6%)
Compliance under assessment at period end	0 (0%)	4 (8%)
Processing time		
Initial certification inspections conducted within 6 months of application	21 (85%)	11 of 17 (65%)[b]
Certification re-inspections conducted within 6 months of due date	44 (85%)	20 of 28 (71%)[c]

a. The decline in the number of overseas inspections conducted is attributed to a pause in overseas GMP Inspections due to COVID-19 pandemic travel restrictions.

b. There were a total of six overseas initial inspections which did not achieve the six month processing timeframe. One inspection was delayed at the request of the manufacturer, as they were not ready for inspection and one inspection was delayed by travel restrictions. The remaining four inspections were delayed due to unavailability of evidence or inspector availability.

c. There were a total of eight overseas re-inspections which did not achieve the six month processing timeframes. These inspections were delayed due to inspection resourcing.

11.3. 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 59 GMP clearance application status

	2018-19	2018-20
	July to June	
	Number (% of Total completed)	
Applications received	6628	7153
Applications completed		
Approved	6252 (88%)	6414 (91%)
Rejected	854 (12%)	637 (9%)
Total completed	7106 (100%)	7051 (100%)

Table 60 Number of GMP Clearance applications received and completed by type from 1 July 2019 to 30 June 2020

Application Category	Applications received	Applications completed
Cancel	8	8
Extend	2131	2115
New	2352	2363
Reactivate	0	29
Variation	2662	2565

Table 61 Number of GMP Clearance applications actioned by pathway from 1 July 2019 to 30 June 2020

Pathway	Applications received	Applications completed	Applications approved	Applications not approved
Compliance Verification	1472	1292	1190	102
Mutual Recognition Agreement	2710	2709	2581	128

12. Recalls

12.1. Medicine recalls

Table 62 Medicine recalls by reason for recall

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Reason for recall		
Adverse reactions	2 (5%)	1 (2%)
Foreign matter	5 (12%)	0
Illegal supply	2 (5%)	2 (3%)
Impurity and degradation	4 (10%)	13 (22%)
Labelling and packaging	14 (34%)	18 (30%)
Micro-organisms	2 (5%)	4 (7%)
pH	0	0
Potency	1 (2%)	4 (7%)
Sterility	0	7 (12%)
Other[a]	11 (27%)	11 (18%)
Total	41 (100%)	60 (100%)

[a] 'Other' includes dissolution, physical defects, observed differences, variable content, diagnostic inaccuracy and wrong product, disintegration/dissolution, GMP non-compliance, transport/storage, bioavailability, preservative efficacy and therapeutic inefficiency. Medical device recalls

Table 63 Medical device (including IVDs) recalls by reason for recall

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Reason for recall		
Adverse incidents	5 (0.8%)	6 (1%)
Diagnostic inaccuracy	66 (11%)	70 (11%)
Electrical defect	23 (4%)	28 (5%)
Illegal supply	1 (0.2%)	2 (0.1%)
Labelling and packaging	131 (22%)	136 (22%)
Mechanical and physical defects	203 (34%)	182 (30%)
Software defects	130 (22%)	151 (25%)
Sterility	3 (0.5%)	3 (0.1%
Other[a]	34 (6%)	36 (6%)
Total	596 (100%)	614 (100%)

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

12.2. Blood and Biological recalls

Table 64 Blood recalls

	2018-19	2019-20
	July to June	
Recalls to hospital level	102	100

Table 65 Biological recalls

	2018-19	2019-20
	July to June	
Recalls to hospital level	29	16

13. Laboratory Testing

The TGA Laboratories conduct post-market monitoring and compliance testing, investigations and reviews, as well as market authorisation assessment of therapeutic goods.

We identify and prioritise therapeutic goods for testing to fulfil regulatory compliance and monitoring requirements, and the transparency and accountability requirements of Government. The testing program also provides flexibility and capacity to provide testing for investigations into problem reports, complaints and urgent public health concerns.

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*. Consumers and health professionals can identify which products have been tested by the TGA, whether they passed or failed, and for those that did fail, what regulatory action was taken. 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. Providing this information has been an important enhancement to the transparency of the Government's regulatory processes and the vital role of the TGA in ensuring the safety, efficacy, performance and quality of medicines and medical devices for Australian consumers.

A significant rise in the failure rates of tested Prescription and Over-the-Counter products was observed during the reporting period. This was predominantly due to the testing of large numbers of Ranitidine samples to determine the extent of nitrosamine contamination in these commonly used products. Further information regarding this testing can be found at www.tga.gov.au/tga-laboratories-testing-ranitidine-medicines. An increase in the failure rate of tested medical devices was also observed in this period when compared to 2018-19. The largest contributor to this rise was an investigation into invasive blood pressure transducers, initiated by adverse event reports received by the TGA.

Table 66 Samples and products tested by type of therapeutic good and percentage which failed

		2018-19	2019-20
		July to June	
Therapeutic good type			
Prescription medicines	Total	1064	1268
	% fail	0.1%	9%
OTC medicines	Total	20	42
	% fail	0%	21%
Complementary medicines[a]	Total	229	137
	% fail	17%	4%
Medical devices	Total	135	128
	% fail	25%	44%
External[a]	Total	29	15
	% fail	14%	13%
Pacific Medicines Testing Program	Total	57	92
	% Fail	21%	16%
Unregistered[b]	Total	208	472
	% fail	69%	21%
Total samples (excluding AHQ samples)		1742	2154
Total samples[c]		2071	2668
Percentage fail		13%	14%
Total number of products tested[d]		857	1044

[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 67 Samples that failed laboratory testing by reason for July 2019 to June 2020

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Complementary medicines	External	Pacific Medicines Testing Program	Total (% fail)
Contamination	5	0	0	0	3	0	0	8 (0.4%)
Formulation	0	8	111	90	1	1	14	225 (10%)
Label and packaging deficiencies	6	0	0	0	2	0	0	8 (0.4%)
Performance	45	0	0	0	0	0	0	45 (2%)
Physical or mechanical properties	0	1	0	0	0	1	1	3 (0.1%)
Unregistered	0	0	0	8	0	0	0	8 (0.4%)
Total	56	9	111	98	6	2	15	297

Table 68 Batch release and export certification

	2018-19	2019-20
	July to June	
Batch releases and certifications		
Batch release[a]	385	426
Export certification[b]	33	84

[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. The number of certificates provided by us therefore depends on the number of requests received.

Table 69 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 70 Compliance with testing timeframes[a] for July 2019 to June 2020

	Priority	Number (% of Total)
Therapeutic good type[b]		
Medical devices	Routine	28 (50%)
	Priority	80 (0%)
	Urgent	20 (25%)
OTC medicines	Routine	21 (71%)
	Priority	21 (100%)
	Urgent	0 (N/A)
Prescription medicines	Routine	161 (67%)
	Priority	225 (80%)
	Urgent	10 (100%)
Complementary Medicines	Routine	115 (37%)
	Priority	22 (77%)
	Urgent	0 (N/A)
Unregistered products	Routine	343 (9%)
	Priority	116 (80%)
	Urgent	4 (0.1%)

[a] Samples involving complex biological assays are excluded from the target turnaround timeframes.

[b] Low numbers of samples within categories may affect compliance percentages.

14. 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, or product suspensions or cancellations. Investigations may also result in criminal or civil court proceedings. All compliance activities have the purpose of protecting public health.

Table 71 Number of compliance actions taken against completed investigations

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Completed investigations		
Criminal prosecution	1 (0.1%)	0 (0%)
Infringement notices	9 (0.3%)	35 (1%)
Warning letters issued[a]	2489 (72%)	3669 (78%)
Goods released under Personal Import Scheme	534 (15%)	338 (7%)
Referred to external agency	86 (3%)	100 (2%)
Referred to the Commonwealth Director of Public Prosecutions	5 (0.1%)	5 (0.1%)
Referred internally	91 (3%)	77 (2%)
No offence identified	248 (7%)	522 (11%)
Total [c]	3463 (100%)	4706 (100%)
Units of goods referred to ABF for destruction[b]	1069946	753897

[a] The category 'warning letters issued' can include goods destroyed as prohibited imports and goods re-exported.

[b] Units refers to single dosage unit e.g. 1 tablet, 1 capsule, 1 tub of powder or a single device.

[c] There can be multiple actions per case resulting in a higher total figure than shown in finalised cases below.

Table 72 Regulatory compliance investigations by number

	2018-19	2019-20
	July to June	
Compliance cases[a]		
Cases received	3658	4983
Cases active	400	1684
Cases finalised	3271	3299

[a] These figures are based on case numbers and not actions taken or offence types.

Table 73 Number of different products investigated

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Therapeutic good type		
Prescription medicines (Schedule 4 and Schedule 8)	1650 (51%)	3233 (72%)
Schedule 9 medicines	10 (0.3%)	43 (0.9%)
Schedule 10 medicines	20 (0.6%)	37 (0.8%)
Medical devices	40 (1%)	753 (17%)
Complementary and homoeopathic medicines	353 (11%)	222 (5%)
OTC medicines	75 (2%)	62 (1%)
Biological and blood products	14 (0.4%)	14 (0.3%)
Other[a]	1074 (33%)	123 (3%)
Total[b]	3236 (100%)	4487 (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 74 Regulatory compliance investigations by special interest categories

	2018-19	2019-20
	July to June	
	Number (% of Total)	
Compliance investigation category		
Unregistered	3544 (96%)	4895 (97%)
Registered	11 (0.3%)	40 (1%)
Counterfeit product	121 (3%)	87 (2%)
Other	17 (0.5%)	1 (0.1%)
Total[a]	3693 (100%)	5023 (100%)

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

Table 75 Number of offence types related to completed cases

	2018-19	2019-20
	July to June	
	Number (% of total)	
Offence type		
Import	4388 (87%)	4938 (91%)
Export	5 (0.1%)	28 (0.5%)
Manufacture	63 (1%)	58 (1%)
Supply	605 (12%)	428 (8%)
Total completed[a]	5061 (100%)	5452 (100%)

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

Table 76 Location of alleged offence by referral type for July 2019 to June 2020

Origin	ACT	NSW	NT	QLD	SA	VIC	WA	TAS	Total
Australian Border Force	52	1092	133	742	221	1554	543	75	4412
External Agencies, Other Regulatory Body, State Health Department	N/A	23	1	10	4	13	5	N/A	56
General public	10	69	2	52	8	61	12	5	219
Sponsor/client, Patient /Practitioner	N/A	8	N/A	2	N/A	12	N/A	N/A	22
TGA internal[a]	3	29	N/A	15	5	9	8	1	70
Total	65	1221	136	821	238	1649	568	81	4779

[a] Referred from within the TGA for investigation as a result of other work, e.g. Conformity assessments, advertising complaints.

15. Pharmacovigilance Inspection Program

Table 77 Pharmacovigilance Inspection Program inspections undertaken and deficiencies identified

	2018-19	2019-20
	July to June	
Compliance investigation category		
Total inspections completed	10	8
Total with completed findings	7	8
Critical deficiencies[a]	1	1
Major deficiencies[b]	34	35
Minor deficiencies[c]	24	23
Average deficiencies per inspection	0 critical 5 major 3 minor	0 critical 4 major 3 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.

[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.

16. Reporting of Medicine Shortages

Table 78 Number of medicine shortage reports[a] by shortage reason

	2018-19	2019-20
	July-June	
	Number (% of Total)	
Shortages Reported		
New – Commercial changes	237 (16%)	47 (3%)
New - Discontinuation	63 (4%)	186 (11%)
New – Manufacturing related	676 (47%)	650 (40%)
New – Other	237 (16%)	422 (26%)
New – Product recall	18 (1%)	10 (1%)
New – Unexpected increase in demand	224 (15%)	329 (20%)
Total	1455 (100%)	1644 (100%)

[a] New reports only, does not include updates of previously reported shortages. Mandatory reporting of all shortages of prescription medicines and select over-the-counter medicines commenced 1 January 2019.

Table 79 Number of medicine shortage notifications processed

	2018-19	2019-20
	July-June	
Notifications processed		
New	1455	1644
Update[a]	2605	4477
Total	4060	6121

[a] Updates of previously reported shortages, including updates to 'Resolved' status. All reports submitted voluntarily, with mandatory reporting of all shortages of prescription medicines and select over-the-counter medicines commencing 1 January 2019.

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Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
https://www.tga.gov.au

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