Australian Government

Department of Health

Therapeutic Goods Administration

Therapeutic Goods Administration

Annual Performance Statistics Report

July 2017 to June 2018

Contents

About the Therapeutic Goods Administration

The 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 2018 there were 89,553 therapeutic goods on the ARTG. 11,032 new products were added to the ARTG 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 biologics.

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 2017 to 30 June 2018, and contribute to annual publications that track our progress against the priorities we have established for the financial year.

Performance highlights: July 2017 to June 2018

Key observations for 2017-18 are summarised below, including trends and notable changes from previous reporting periods.

As part of our 2017-18 activity, we have continued to implement the Australian Government's Response to the Review of Medicines and Medical Devices Regulation (MMDR). Following the passage of amendments to the Therapeutic Goods Regulations 1990 that follow on from commencement of the *Therapeutic Goods Amendment (2016 Measures No.1) Act 2017* and the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018*, this reporting period now includes new data sets in relation to:

- Orphan Drugs
- Special Access Scheme
- Authorised Prescriber Scheme
- Priority pathways for medicines and medical devices
- Pharmacovigilance Inspection Program
- Provisional approval pathway for prescription medicines
- An automated notification process for very low risk changes to biologicals and registered medicines
- A pathway for use of un-redacted assessment reports from Comparable Overseas Regulators.

Reforms

Orphan drug program reform

Our reformed orphan drug program came into effect on 1 July 2017 and created a fairer program that aligns more closely with international criteria without impeding the availability of drugs for rare diseases. The reforms have also expanded the program to include new dosage form medicines.

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 patients who would not otherwise be able to access them. The incentive is in the form of a waiver of application and evaluation fees.

Special Access Scheme

A new Special Access Scheme (SAS) pathway – Category C – was established in July 2017. Category C is a notification pathway allowing certain unapproved therapeutic goods that are deemed to have an established history of use to be supplied to an individual patient or class of patients without TGA approval. Under this pathway, health practitioners may be authorised to supply certain unapproved therapeutic goods for a particular indication as specified in legislative instruments. The introduction of Category C has enabled more streamlined access under the SAS.

Authorised Prescriber Scheme

A change to the application process of the Authorised Prescriber Scheme was implemented on 1 July 2017 to streamline access to unapproved therapeutic goods. This change removed the requirement for a medical practitioner to resubmit their clinical justification to the TGA, as this is required to be submitted to, and evaluated by, a Human Research Ethics Committee or specialist college. The duration of approval can now also be extended for therapeutic goods which are deemed to have an established history of use.

Priority review of prescription medicines

A new priority review pathway was also implemented on 1 July 2017. Priority review involves faster assessment of vital and life-saving prescription medicines for which a complete data dossier is available. The target timeframe of 150 working days is up to three months shorter than the standard prescription medicines registration process. The Priority review pathway operates with new and flexible business processes in order to facilitate faster assessment for registration, while maintaining our high standard for efficacy, safety and quality.

Pharmacovigilance Inspection Program

The inspection program involves TGA representatives interviewing sponsors and reviewing documents in order to assess sponsors' compliance with pharmacovigilance requirements. The program is largely based on the UK Medicines and Healthcare products Regulation Agency's successful pharmacovigilance inspection program, but also takes into consideration unique Australian factors. The launch of the program in September 2017 was preceded by substantial stakeholder engagement and consultation, particularly with medicine sponsors. The rollout was supported by a series of information sessions held around the country.

Provisional approval of prescription medicines

In March 2018, a new provisional approval pathway for prescription medicines was implemented. This pathway allows sponsors to apply for time-limited provisional registration on the ARTG on the basis of preliminary clinical data, providing access to certain 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.

Provisional registration is limited to a maximum of six years and will automatically lapse at the end of a specified period unless sponsors are able to demonstrate that they have met the conditions imposed on the provisional registration. Sponsors may apply for full registration when sufficient clinical data to confirm the safety and efficacy of the medicine are available.

Automated notifications for very low risk changes to registered medicines

A 'notifications' process was introduced in 2017 for very low risk changes to biologicals and to registered medicines. This process was implemented in two stages:

- notifications to registered non-prescription medicines, launched in July 2017
- notifications to biologicals and prescription medicines, launched in December 2017.

The new notifications processes are part of our improved risk-based approach to the management of variations.

Under the notifications process, an applicant uses an electronic form to request that certain types of changes be made to their medicines. For registered medicines, the request is automatically processed once it has passed electronic validation and the relevant fee has been paid. Manual processing is still required for notifications to biologicals.

Comparable Overseas Regulator report-based process

In January 2018, we implemented the Comparable Overseas Regulator report-based process for prescription medicines, replacing the Category 2 application process.

Report-based applications can relate to all types of new prescription medicines, including new chemical entities, new fixed dose combinations, generic medicines, biological medicines and biosimilars. This process can additionally be used for variations to existing medicines, including extension of indications or new dosage forms and changes to Product Information documents that would normally require evaluation of clinical data.

Prescription medicines

Fourteen priority review determinations and two provisional determinations were approved under the new priority review pathway and the new provisional approval pathway respectively. Of the 14 medicines receiving priority review determination, five were also approved for registration in 2017-18. The median timeframe for these registrations via the priority review pathway was 98 working days, against a target timeframe of 150 working days.

Eleven orphan drug designations were approved in 2017-18 under the reformed orphan drug program, with five additional designations approved under the previous orphan drug program (where the designation application was received prior to 1 July 2017). Twenty-one orphan drugs were approved in 2017-18, including one that received its designation under the reformed program.

A new prescription medicines minor variations form was also introduced, providing a single electronic form allowing sponsors to apply for minor variations.

Over-the-counter medicines

The total number of new medicine applications received was substantially higher than in 2016-17, with increases in the numbers of lower risk (N1, N2 and N3) and higher risk (N5) applications. The total number of applications received to vary existing medicines also increased substantially. The number of negligible risk (C1) applications decreased but was largely offset by the number of negligible-risk (CN) applications received (new notification application type implemented on 1 July 2017). The number of low risk variation (C2) applications increased substantially, in part due to receipt of applications for changes to labelling for compliance with the new labelling Order (Therapeutic Goods Order No. 92). The numbers of higher risk variation (C3 and C4) applications were consistent with previous years.

Median approval times for all new medicine application types were shorter than in 2016-17, but were consistent with previous years. Median approval times for higher risk variation (C2, C3, and C4) applications were longer than in 2016-17. For C2 applications this can be attributed to the large increase in the number of C2 applications received. Four out of five approved C3 applications were within target time and for all other application types the percentage of applications processed within target time continued to be at or close to 100%.

Listed medicines

The number of new listed medicines on the ARTG increased by 211 in 2017-18. This may be partly attributed to the introduction of permitted indications in March 2018.

The number of post-market compliance reviews completed decreased in 2017-18 due to a large and complex targeted review project of listed sunscreens having been undertaken over the course of the year. Investigations, which arise from complaints from the public, industry referrals and adverse event reporting, decreased. Investigations are assessed using a risk prioritisation system, and where required, will give rise to a compliance review being initiated.

Labelling, advertising and evidence continue to be major categories of compliance issues. No products were found to have issues posing a potential risk to consumer safety, compared with 22 products in 2016-17.

Biologicals

The number of new and variation applications has stabilised. The number of Technical Master File variations has decreased significantly over 2017-18, back to expected levels. The spike in numbers during 2016-17 was the result of major process alignment activity completed by the public cord blood banks during that year. The first Class 4 biological applications, representing a new class of therapeutic goods were received.

Medicine and vaccine adverse event reports

The total number of medicine and vaccine adverse event reports rose by 1,882 from 2016-17. The mean number of reports received weekly rose from 380 to 416 and the proportion of reports received from each category of reporter broadly matched 2016-17. The transition to a new Adverse Event Management System was initiated on 22 June 2018.

Medical device conformity assessment

The number of Conformity Assessment applications received during 2017-18 significantly increased compared with numbers submitted in 2016-17. We completed 273 applications compared with 204 in 2016-17, and have continued to refine and develop new guidance for industry which is resulting in better submissions and improved application processing.

Medical device incident reports

Medical device adverse event reports received increased by 452 in 2017-18. Media attention and the Senate Inquiry into transvaginal mesh accounts for an increase in reports by patients and carers, while continued education of health professionals on the value of reporting adverse events has led to an increase by them and sponsors.

Exports

The number of new export medicine listing applications and variations remained constant over the last two reporting periods. The number of export certificates for medicines increased by 14%, having dropped by 25% in 2016-17. There was again an increase in the number of device certificates issued (22%).

All human blood and tissue permits were released within the 24 hour target timeframe to ensure that emergency demands overseas were met.

Access to unapproved therapeutic goods

A notable change for this reporting period was the introduction of the aforementioned Special Access Scheme (SAS) pathway – Category C. There were 14,560 Category C notifications for medicines which resulted in sizeable falls in the other two SAS pathways. Overall there was a net decrease of 564 SAS notifications/ applications in 2017-18 with decreases observed for medicines and biologicals, and a small increase for devices compared to 2016-17.

Medicines and biologicals manufacturing

The number of inspections of Australian manufacturers increased by 25 in 2017-18 due to the number of new licence and variation applications received, as well as the number of re-inspections performed. The number of initial inspections conducted within 3 months of application for Australian manufacturers increased from 85% to 96%, which is due to manufacturers being ready for the inspection and the prioritisation of these inspections within the target timeframe. Similarly, re-inspections of Australian manufacturers conducted within 6 months increased from 61% to 72%, due to the prioritisation of these inspections to occur within the target timeframe. The number of inspections conducted for overseas manufacturers increased from 58 to 84, due to the number of re-inspections conducted.

Demand for Good Manufacturing Practice (GMP) clearances remained high with 5,327 applications received during 2017-18 compared with 5,471 in 2016-17. The decrease of 144 applications correlates to the decrease in rejected applications indicating an improvement in the quality of applications received. This is attributed to increased educational activities conducted by the TGA.

Recalls

Overall, the total number of recalls remained steady. There was a slight decrease in the number of medical device recalls, but a notable increase from two to 25 recalls for biological products. This may be attributed to increased stakeholder awareness of the overall regulatory framework for this product category.

Laboratory testing

A revised risk based process for targeting products for testing was implemented in 2017-18. The revised process resulted in improved accountability and transparency for the testing performed by the Laboratories Branch which is evidenced by the significant increase in the number of individual products tested this year. An increase was also seen in the number of complementary medicines tested as a result of improved targeting of products with a higher risk of non-compliance.

The first testing campaign under the Pacific Medicines Testing Program commenced in the second half of the year. The campaign included five Pacific Island Countries and focussed on antibiotics, paracetamol, and medications for diabetes and cardiovascular disease.

Regulatory compliance

Compliance and investigation and matters increased by 3.2% in 2017-18, with 2,982 matters completed. The largest contributor to the number of matters handled and investigated continues to be referrals from Australian Border Force in relation to the importation of unapproved prescription medicines.

1. 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;
- payment of fees was received; or
- 'mutual clock stop' periods agreed with the applicant or unless otherwise specified.

Under the *Therapeutic Goods Act 1989* (the Act), TGA working days exclude 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.

2. 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 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.
Note: the timeframes quoted above are statutory timeframes. The new 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.		
Category 2 *(until 31 December 2017)*	An application accompanied by two independent evaluation reports from comparable overseas regulators in whose jurisdiction the product is approved for the same indication.	Legislated timeframe: 20 working days for notification of whether the application has passed preliminary assessment and 175 working days to notify the applicant of the decision.
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: 120 working days · COR-B: 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.

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.

2.1. Approval times

Table 1 Prescription medicine application approval time for July 2017 to June 2018

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]	41	255	205	209	104-245
B: New fixed-dose combination	5	255	202	192	169-236
C: Extension of indication[a]	53	255	185	193	85-242
D: New generic medicine	104	255	182	174	115-254
F: Major variation	42	255	192	196	130-254
G: Minor variation	1	255	250	250	250
H: Minor variation	6	255	162	164	145-171
J: Changes to Product Information requiring the evaluation of data	84	255	143	148	5-242
Additional trade name					
E: Additional trade name (ATN)	69	45	26	27	4-43

[a] Timeframes and submission totals for Category 1 Types A and C include submissions processed via the priority review pathway.

Table 2 Prescription medicine median approval time comparisons

Application type	Legislated timeframe	Median approval time (TGA working days) 2016-17	2017-18
Category 1			
A: New chemical entity/New biological entity/Biosimilar	255	208	209
B: New fixed-dose combination	255	203	192
C: Extension of indication	255	202	193
D: New generic medicine	255	172	174
F: Major variation	255	185	196
G: Minor variation	255	0	250
H: Minor variation	255	143	164
J: Changes to Product Information requiring the evaluation of data	255	140	148
Additional trade name (ATN)			
E: Additional trade name (ATN)	45	36	27
Minor Variations			
Category 3			
G: Minor variation[a]	45	26	39
H: Minor variation[b]	45	23	32
Safety-related request [(SRR)]	n/a	21	32
Self-assessable request [(SAR)]	45	14	33
Minor editorial change [(MEC)]	45	20	26
Correction [9D(1)]	n/a	62	56

[a] The type G minor variations differ from type H minor variations in that they result in a new ARTG entry.

[b] 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 Submissions received 2016-17 and 2017-18

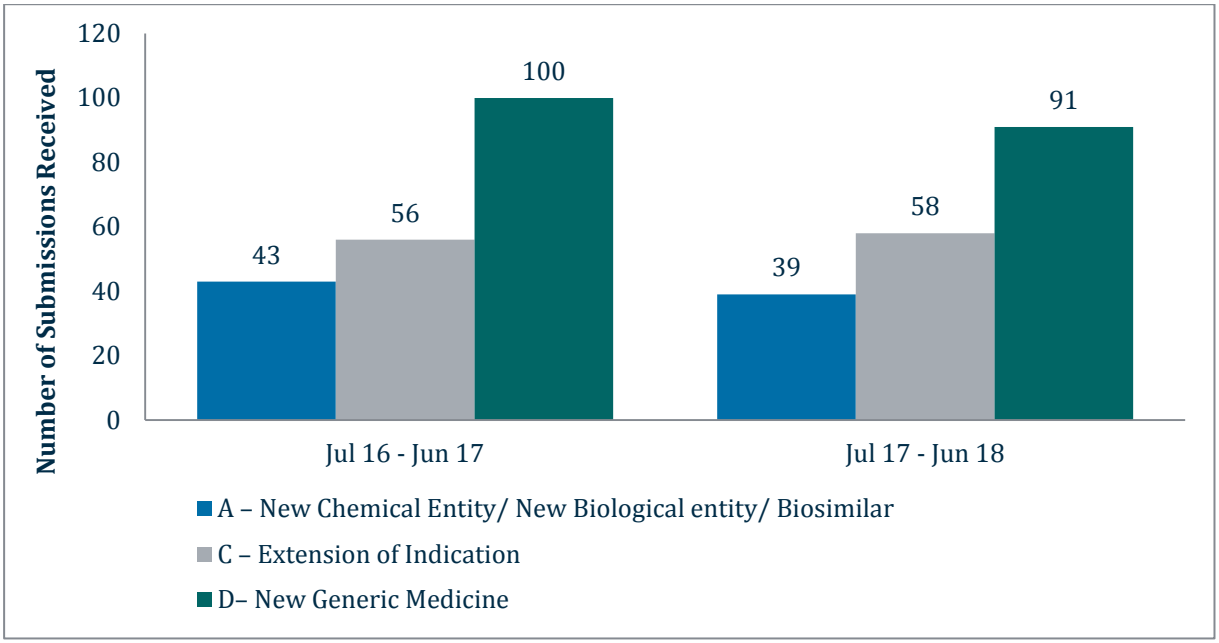


Figure 2 Mean approval times 2016-17 and 2017-18

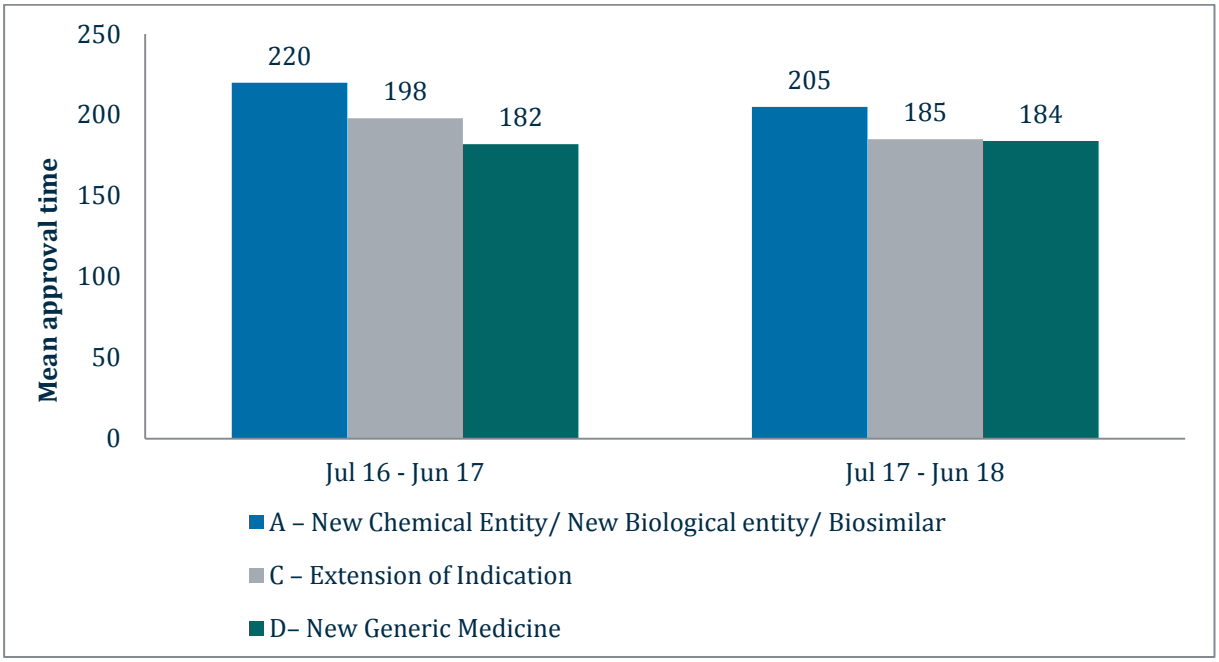
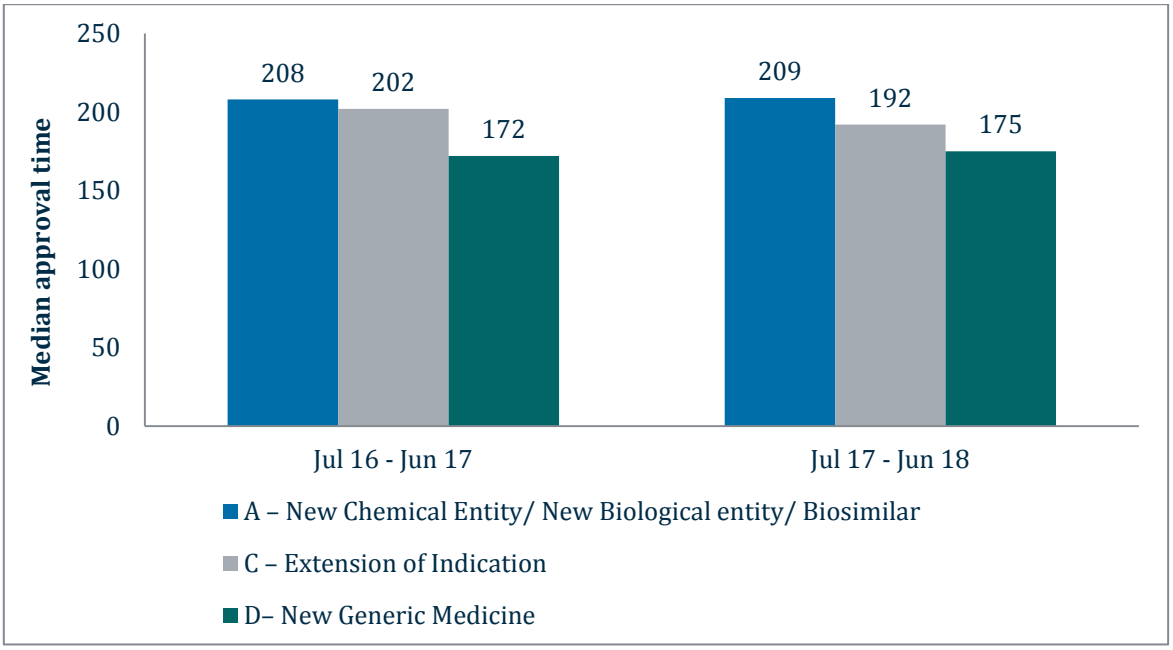


Figure 3 Median approval times 2016-17 and 2017-18



2.2. Submission outcomes

Table 3 Number of completed prescription medicine submissions by type and outcome for July 2017 to June 2018

Submission Type	Approved	Withdrawn	Rejected	Total
A: New chemical entity/New biological entity/Biosimilar	41	5	0	46
B: New fixed-dose combination	5	0	0	5
C: Extension of indication	53	2	1	56
D: New generic medicine	104	10	2	116
E: Additional Trade Name	69	2	0	71
F: Major variation	42	0	0	42
G: Minor variation (Category 1)	1	0	0	1
G: Minor variation (Category 3)	115	2	1	118
H: Minor variation (Category 1)	6	0	0	6
H: Minor variation (Category 3)	1,311	21	0	1,332
J: Changes to Product Information	84	1	0	85
Safety-related request [K(SRR)]	658	9	0	667
Self-assessable request [H(SAR)]	967	18	0	985
Minor editorial change [K(MEC)]	171	6	0	177
Correction [H9D(1)]	71	8	0	79
Notification [Y]	732	2	0	734
Total	4,430	86	4	4,520

2.3. Other applications

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, we may seek approval to supply a product when it doesn't meet a particular standard.

Table 4 Number of other prescription medicine applications

	2016-17	2017-18
	July to June	
Exemptions to comply with a standard [N(S14)]		
Approved	89	67
Rejected	1	0
Total (excluding withdrawals)	90[a]	67

[a] Withdrawals included in total for the 2016-17 reporting period.

2.4. Orphan drug designations

Reporting on orphan drugs for 2017–18 reflects those submitted through the new program which applies to orphan drug designation applications lodged from 1 July 2017, as well as those submitted under the previous program but approved after the new program came into effect. The eligibility criteria for the previous orphan drug program applied to all applications submitted prior to 1 July 2017, regardless of the designation approval date.

A prescription medicine must have a valid orphan drug designation to be eligible for a waiver of application and evaluation fees.

Table 5 Number of orphan drug designations

	2016-17[a]	2017-18
	July to June	
Number of designations approved under the previous orphan drug program (designation application received prior to 1 July 2017)	29	5
Number of designations approved under current orphan drug program (designation application received from 1 July 2017)	0	11
Total	29	16

[a] The figures for 2016–17 reported represents orphan drugs approved under the previous program. Eligibility criteria changed with introduction of the new program. For this reason, figures for orphan drugs approved prior to and after 1 July 2017 are not directly comparable.

Table 6 Number of orphan drug registrations

	2016-17		2017-18[a]	
	July to June			
Application Type	Number Approved	Median approval time (TGA working days)	Number Approved	Median approval time (TGA working days)
A: New chemical entity/New biological entity/Biosimilar	9	210	9	213
C: Extension of Indications	5	185	10	198
F: Major Variation	1	134	2	185
Total	15	196	21[b]	197

[a] Includes orphans designated under the previous orphan drug program (where the designation application was lodged before 1 July 2017) and the new program (where the designation application was lodged from 1 July 2017).

[b] One new biological entity was registered under the new orphan drug program during 2017-18. This product also had a priority review determination.

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 above.

2.5. Priority review pathway

A prescription medicine must have a valid priority review determination before it can be evaluated for registration under the priority review pathway. 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 Priority review determinations granted from July 2017 to June 2018

Priority review determinations approved	
Application type (proposed)	Approved
A: New chemical entity/New biological entity/Fixed dose combination	4
C: Extension of Indications	10
Total	14

Table 8 Medicines approved through the priority review pathway[a] between July 2017 and June 2018

Priority Review Registration Approvals		
Application Type	Number approved	Median approval time (TGA working days)
A: New chemical entity/New biological entity/Fixed dose combination	1	104
C: Extension of Indications	4	97
Total	5	98

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

Priority review registrations and approval times quoted in Table 8 are also included in the total number of applications reported in each respective application category in the tables and figures above.

2.6. Provisional approval pathway

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 Provisional determinations granted from March 2018 to June 2018

Provisional determinations approved[a]	
Application type (proposed)	Approved
A: New chemical entity/New biological entity/Fixed dose combination	1
C: Extension of Indications	1
Total	2

[a] No applications for provisional registration have been approved as at 30 June 2018.

3. Over-the-counter medicines

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

Table 10 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

Application category	Definition	Timeframe in 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

3.1. Approval times

We aim to have 80% of applications completed within target timeframes.

Table 11 Median approval time for OTC medicine applications

	2016-17	2017-18
	July to June	
New medicine applications (days)		
N1	27	25
N2	43	35
N3	94	74
N4	106	55
N5	192	162
Change applications (days)		
C1	7	4
C2	14	31
C3	14	72
C4	86	95

Table 12 OTC medicine approval time against target time by application category for July 2017 to June 2018

Application type	Number completed	Range	Mean	Median	% within target
New medicines					
N1	144	1-54	25	25	96
N2	5	34-39	36	35	100
N3	37	31-184	82	74	97
N4	19	49-204	85	55	95
N5	8	152-185	167	162	100
Change applications					
C1	202	0-26	6	4	99
C2	386	0-70	29	31	99
C3	5	12-124	60	72	80
C4	4	46-159	99	95	100

Table 13 Percentage of OTC medicine applications processed within target time

	2016-17	2017-18
	July to June	
New medicine applications (%)		
N1	100	96
N2	100	100
N3	100	97
N4	100	95
N5	100	100
Change applications (%)		
C1	97	99
C2	99.6	99
C3	100	80
C4	100	100

3.2. Applications

3.2.1 New OTC medicine applications

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

	2016-17	2017-18
	July to June	
New medicine applications		
N1	108	169
N2	5	16
N3	44	64
N4	23	23
N5	6	8
Total	186	280
Change applications		
CN	-	171
C1	387	190
C2	276	438
C3	7	7
C4	2	3
Total	672	809

3.2.2 Completed applications

Table 15 New OTC medicine applications completed and outcomes

	2016-17	2017-18
	July to June	
N1		
Approved	93	144
Rejected	0	0
Withdrawn by sponsor	1	7
Returned/failed screening	0	0
Total	94	151
N2		
Approved	7	5
Rejected	0	0
Withdrawn by sponsor	1	6
Returned/failed screening	0	0
Total	8	11
N3		
Approved	29	37
Rejected	0	0
Withdrawn by sponsor	2	1
Returned/failed screening	3	8
Total	34	46
N4		
Approved	29	19
Rejected	0	1
Withdrawn by sponsor	0	3
Returned/failed screening	6	2
Total	35	25
N5		
Approved	8	8
Rejected	0	0
Withdrawn by sponsor	0	2
Returned/failed screening	0	1
Total	8	11

Table 16 OTC change applications completed and outcomes

	2016-17	2017-18
	July to June	
C1		
Approved	396	202
Rejected	0	0
Withdrawn by sponsor	10	2
Returned/failed screening	0	0
Total	406	204
C2		
Approved	226	386
Rejected	0	0
Withdrawn by sponsor	7	11
Returned/failed screening	1	2
Total	234	399
C3		
Approved	7	5
Rejected	0	0
Withdrawn by sponsor	1	0
Returned/failed screening	2	1
Total	10	6
C4		
Approved	1	4
Rejected	0	0
Withdrawn by sponsor	0	0
Returned/failed screening	0	0
Total	1	4

3.2.3 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

	2016-17	2017-18
	July to June	
Requests for advice for the purpose of listing a medicine as a pharmaceutical benefit		
B1	1	0
B3	1	0
Total	2	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	25	10
Rejected	1	0
Total	26	10

4. 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

	2016-17	2017-18
	July to June	
New medicines		
Approved	6	5
Rejected	1	1
Withdrawn	3	0
Returned/failed screening	0	0
Total new applications completed	10	6
Variations		
Approved	20	19
Rejected	1	4
Withdrawn	3	0
Returned/failed screening	0	0
Total variations completed	24	23
Application for consent to import, supply or export goods under section 14/14A of the Act[a]		
Approved	1	12
Rejected	0	0
Total applications completed	1	12

[a] Applications can be made for consent to import, supply or export goods under section 14/14A of the *Therapeutic Goods Act 1989*.

5. Listed medicines

5.1. New ingredients permitted for use in listed medicines

Table 19 New listed medicine ingredient applications by outcome

	2016-17	2017-18
	July to June	
Application outcome		
Approved	79	24[a]
Rejected	0	0
Withdrawn	1	3
Returned/failed screening	0	1
Total completed	80	28

[a] The significant decrease is due to a large number of ingredients that were made available for excipient use following TGA initiated assessments in 2016-17.

5.2. New listed medicines

Table 20 New listed medicines

	2016-17	2017-18
	July to June	
New listed medicines	1,581	1,792

Table 21 Listed medicine variations under section 9D of the *Therapeutic Goods Act 1989*

Section 9D of the *Therapeutic Goods Act 1989* provides for variations to be made to an entry on the ARTG in a set of limited and prescribed circumstances. These circumstances include where information included on the ARTG is incomplete or incorrect.

	2016-17	2017-18
	July to June	
Medicine variation		
Approved	85	91
Rejected	4	5
Total	89	96

Table 22 Listed medicine applications under section 14/14A of *the Therapeutic Goods Act 1989*

	2016-17	2017-18
	July to June	
Application		
Exemption granted[a]	7	5
Rejected	2	0
Total	9	5

[a] Sponsors can apply for certain exemptions under Section 14 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.

5.2.1 Investigations

Investigations include 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 assessed and triaged based on a risk management approach to provide the greatest overall benefit for the Australian public. Investigations may be completed through a number of mechanisms, such as initiating a targeted review or referral to another area of the TGA.

Table 23 Listed medicine investigations undertaken and outcomes

	2016-17[a]	2017-18
	July to June	
Initiated investigations	80	56
Completed investigations		
Medicines prioritised for targeted review	60	50
Referred to another TGA area or government organisation	3	4
No further action taken[b]	21	10
Total completed investigations	84	64

[a] The values for 2016-17 shown here differ from those provided in the Annual Performance Statistics Report 2016-17, which mistakenly reported the aggregate values for 2015-17 as the 2016-17 values. This was an inadvertent error in the preparation of the 2016-17 report that was discovered in the preparation of the 2017-18 report.

[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; the complaint was not justified and did not warrant further action; or advice was provided to the complainant.

5.2.2 Compliance reviews

Listed medicines are not evaluated by the TGA before they are included on the ARTG. However, a proportion is 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.

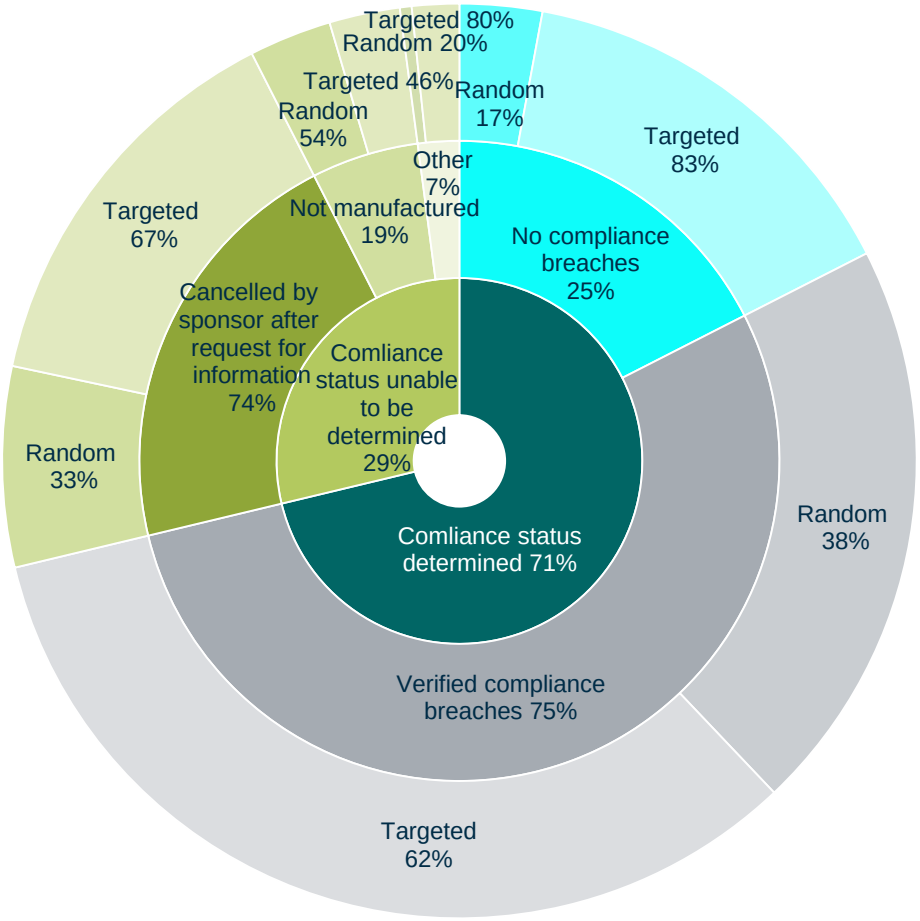
Table 24 Listed medicine reviews by type

	2016-17	2017-18
	July to June	
Initiated reviews		
Targeted reviews	504	82
Random reviews	87	143
Total	591	225
Reviews on hand	189	173
Completed reviews		
Targeted reviews	421	162
Random reviews	130	81
Total	551	243

Table 25 Completed listed medicine reviews by outcome

	2016-17	2017-18
	July to June	
Compliance status determined		
Medicines with no compliance breaches	87	42
Medicines with verified compliance breaches	330	129
Sub-total	417	171
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	74	51
Medicines not yet manufactured	58	13
Other	1	5
Sub-total	133	69
Product not a therapeutic good	1	3
Total completed	551	243

Figure 4 Outcomes of compliance reviews by reason for initiation[a]



[a] In this period, we performed a slightly higher proportion of random reviews than in 2016-17. A number of targeted compliance projects that had been initiated in the previous period drew to a close and we increased our focus on random reviews to gather new data for detecting and targeting compliance issues. Of the reviews where we were able to determine a compliance status, 75% had verified compliance breaches, which is consistent with the non-compliance rate from the previous period.

Table 26 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.

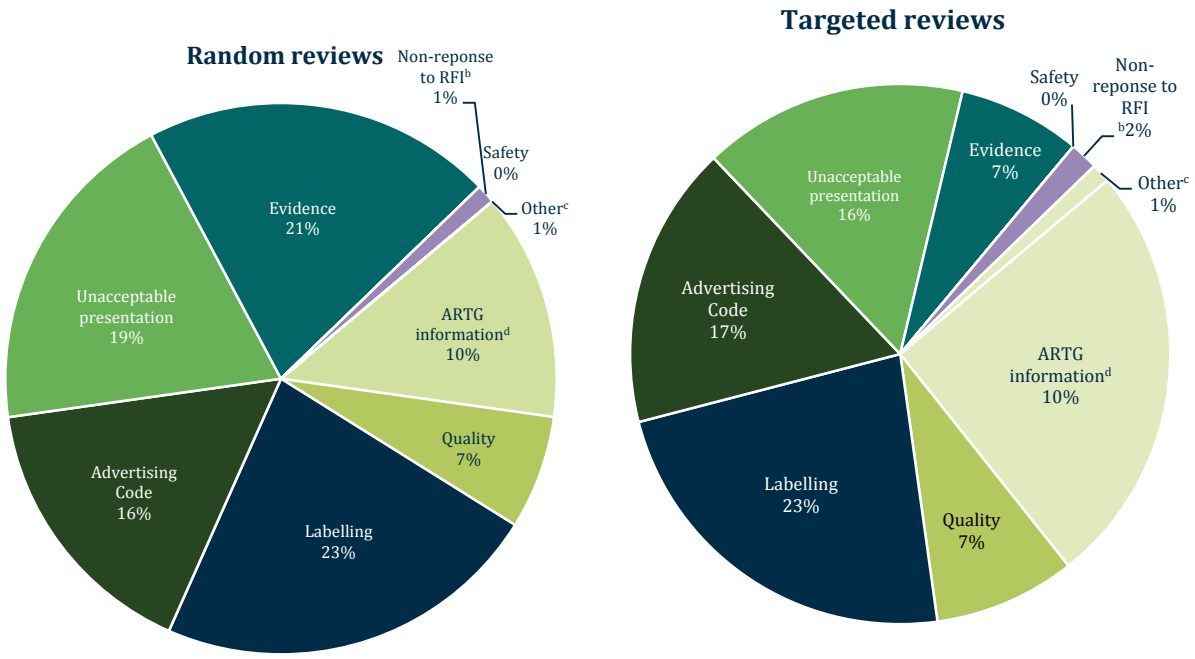
	2016-17	2017-18
	July to June	
Type of compliance issue		
Information provided in ARTG entry	119	69
Manufacturing, quality and/or formulation	62	27
Labelling	94	58
Advertising	86	59
Unacceptable presentation	140	63
Evidence[a]	180	50
Safety[b]	22	0
Non-response to a request for information[c]	8	5
Other[c]	4	2

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

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

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

Figure 5[a] Types of compliance issues identified by reason for initiation



[a] Figure 5 shows the types of compliance issues that are identified through reviews which 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, 66% of randomly-selected non-compliant medicines were found to have insufficient evidence to support the medicine indication, yet this breach accounted for 21% of the total breaches identified across all randomly-selected non-compliant medicines.

[b] 'RFI' refers to 'Requests For Information'.

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

[d] '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.

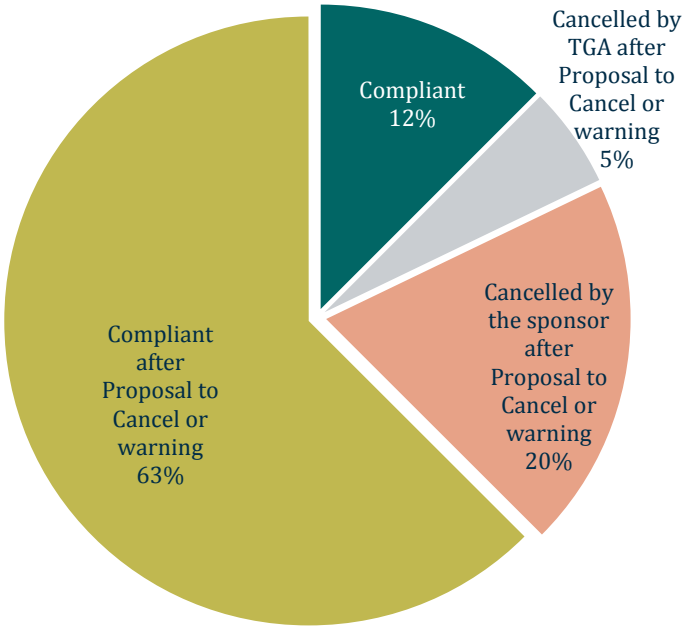
Table 27 Actions taken following listed medicine reviews

	2016-17	2017-18
	July to June	
Actions following a Request for Information		
Medicines found to be compliant and review concluded	87	42
Medicines cancelled by the TGA without a proposal to cancel notice	0	0
Proposal to cancel notice or warning[a] sent by the TGA	330	129
Total	417	171
Actions following Proposal to Cancel notice[b]		
Medicines cancelled by the TGA	17	10
Medicines cancelled by sponsors after being notified of compliance breaches	84	45
Reviews concluded after compliance breaches were addressed	229	74
Total	330	129

[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 are considered the same for reporting purposes.

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

Figure 6[a] Outcomes of completed compliance reviews



[a] Figure 6 shows that 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 increase in the number of listed medicines cancelled by the TGA following a Proposal to Cancel or warning letter (5%) compared with the previous period (4%). The high proportion of listed medicines that are brought back into compliance after a Proposal to Cancel shows that industry is willing to work with us to ensure the supply of listed medicines on the ARTG is compliant.

6. Biologicals and blood components

6.1. Inclusion of biologicals

Table 28 Applications for biologicals[a] received and on hand

	2016-17	2017-18
	July to June	
Applications received		
Technical Master File (TMF)[b] new	0	0
TMF annual updates	5	3
TMF variations	20	14
TMF notifications	27	8
Plasma Master File[c] annual updates	11	10
Biological Class 2 – new applications	4	1
Biological Class 3 – new applications	0	0
Biological Class 4 – new applications	0	2
Biological Class 2 – variations	14	22
Biological Class 3 – variations	1	5
Total received	82	65
Applications on hand		
TMF new	1	0
TMF annual updates	4	2
TMF variations	7	4
TMF notifications	0	0
Plasma Master File annual updates	4	7
Biological Class 2 – new applications	6	2
Biological Class 3 – new applications	3	1
Biological Class 4 – new applications	0	2
Biological Class 2 – variations	2	3
Biological Class 3 – variations	0	0
Total on hand	27	21

[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 29 Completed applications for biologicals

	2016-17	2017-18
	July to June	
Biologicals applications		
Technical Master File (TMF) new	1	1
TMF annual updates	5	2
TMF variations	19	8
TMF notifications	27	8
Plasma Master File annual updates	7	8
Biological Class 2 – new applications	1	3
Biological Class 3 – new applications	1	0
Biological Class 4 – new applications	0	0
Biological Class 2 – variations	18	22
Biological Class 3 – variations	2	5
Total completed	81	57

7. Medicine and vaccine adverse event reports

7.1. Adverse medicine and vaccine reaction notifications

Table 30 Source of notifications of medicine and vaccine adverse reactions[a]

	2016-17	2017-18
	July to June	
Reports with clear causality by reporter		
Hospitals	1,850	1,952
Companies	9,194	11,333
General practitioners	573	875
Specialists	245	224
Pharmacists	1,063	975
Members of the public	1,104	1,170
Nurses, dentists, complementary healthcare practitioners	157	260
State/Territory Health departments	3,274	3,459
Reports withdrawn, or rejected, or without clear causality		
	2,276	1,370
Total received	19,736	21,618
Mean number of reports received weekly	380	416
Vaccine reports included in this table	4,020	4,327

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

8. Medical devices

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

- **Conformity assessment:** 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 (and in some cases must) be undertaken by the TGA, or we may recognise conformity assessment certification from 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 (typically demonstrated through conformity assessment certification).
- **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. The TGA is yet to receive an application for priority review.
- **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.

8.1. Conformity assessment

8.1.1 Applications

Table 31 Number of conformity assessment applications (medical devices including IVDs)

	2016-17	2017-18
	July to June	
Conformity assessment applications		
Applications received	242	309
Applications on hand	213	251
Applications completed	204	273

8.1.2 Outcomes

Table 32[a] Outcomes of conformity assessment applications

	2016-17	2017-18
	July to June	
New		
Approved	37	58
Rejected	1	1
Withdrawn/ Lapsed	20	35
Variation (changes and re-certifications)		
Approved	124	166
Rejected	2	1
Withdrawn/ Lapsed	20	12
Total	204	273

[a] The table has been broken down into 'New' and 'Variation' assessment application to provide additional transparency. In reviewing the changes in the reporting, the final total was increased by one.

8.1.3 Processing timeframes

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

Table 33 TGA processing times for new devices and variations

	2016-17	2017-18
	July to June	
New devices		
Mean TGA processing time (days)	129	131
Median TGA processing time (days)	167	189
Variations (changes and recertifications)		
Mean TGA processing time (days)	114	110
Median TGA processing time (days)	101	95

8.2. Inclusion of medical devices (including IVDs)

8.2.1 Applications

Table 34 Applications for inclusion – medical devices (including IVDs)

	2016-17	2017-18
	July to June	
Class I medical devices[a]		
Applications received	2,514	4,805
Applications completed	2,431	4,804
Class I measuring medical devices		
Applications received	51	62
Applications completed	50	64
Applications on hand[b]	4	5
Class I sterile medical devices		
Applications received	246	255
Applications completed	255	240
Applications on hand[b]	3	7
Class IIa medical devices		
Applications received	1,160	1,219
Applications completed	1,178	1,191
Applications on hand[b]	51	92
Class IIb medical devices		
Applications received	666	650
Applications completed	682	568
Applications on hand[b]	34	132
Class III medical devices		
Applications received	343	406
Applications completed	471	378
Applications on hand[b]	180	208
Class III Joint Reclassification medical devices		
Applications received	0	0
Applications completed	203	88
Applications on hand[b]	94	5

	2016-17	2017-18
	July to June	
Active Implantable Medical Devices (AIMD)		
Applications received	48	24
Applications completed	87	34
Applications on hand[b]	23	10
Class 1 IVDs[c]		
Applications received	94	74
Applications completed	91	76
Applications on hand[b]	4	2
Class 2 IVDs		
Applications received	96	81
Applications completed	94	80
Applications on hand[b]	12	13
Class 3 IVDs		
Applications received	49	58
Applications completed	45	60
Applications on hand[b]	15	14
Class 4 IVDs		
Applications received	15	27
Applications completed	15	27
Applications on hand[b]	0	1

[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.

8.2.2 Outcomes

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

Table 35 Outcomes of medical device applications by classification

	Number of applications					
	2016-17			2017-18		
Device Classification	Approved/ Accepted	Rejected/ Lapsed	Withdrawn	Approved/ Accepted	Rejected/ Lapsed	Withdrawn
Class I	2,431	0	0	4,804	0	0
Class I Measurement	44	2	4	60	0	4
Class I Sterile	248	0	7	222	0	18
Class IIa	1,128	6	44	1,138	7	46
Class IIb	659	3	20	513	9	46
Class III	398	18	55	306	17	55
Class III Reclassification	152	3	48	59	15	14
AIMD	87	0	0	33	0	1
Class 1 IVD	84	0	7	73	0	3
Class 2 IVD	71	2	21	75	0	5
Class 3 IVD	37	0	8	58	0	2
Class 4 IVD	14	0	1	27	0	0

8.2.3 Processing times

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 36 Processing times for medical device application audits (including IVDs)

	2016-17			2017-18		
	Number of applications	Sponsor days	TGA days[a]	Number of applications	Sponsor days[b, d]	TGA days[a, d]
Mean Processing Time						
Medical devices						
Applications completed without audit	2,105			2,021		
Non-compulsory audit[c]	310	42	55	197	58	58
Level 1 compulsory audit	40	25	18	27	23	33
Level 2 compulsory audit	471	74	159	318	79	83
IVDs						
Applications completed without audit	77			115		
IVD non-compulsory audit	10	35	46	5	34	57
IVD compulsory audit	82	29	39	56	29	81
Median Processing Time						
Medical devices						
Applications completed without audit	2,105			2,021		
Non-compulsory audit[c]	310	27	24	197	33	24
Level 1 compulsory audit	40	23	13	27	22	23
Level 2 compulsory audit	471	60	155	318	54	47
IVDs						
Applications completed without audit	77			115		
IVD non-compulsory audit	10	22	36	5	21	23
IVD compulsory audit	82	18	29	56	24	64

[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.

8.3. Post-market monitoring

8.3.1 Compliance reviews

As Class I medical devices are automatically included on the ARTG, we undertake post-market compliance reviews for these devices. This includes restricted word reviews, where applications for Class I devices are identified by the use of specific words indicative of risk, or listing issues relating to the inclusion of the device.

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 37 Restricted word Class 1 medical device and targeted compliance reviews

	2016-17	2017-18[b]
	July to June	
Restricted word reviews		
Reviews completed	54	122
Reviews commenced	55	122
Reviews on hand	1	9
Targeted compliance reviews[a]		
Reviews completed	35	166
Reviews commenced	45	211
Reviews on hand	175	229

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

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

8.3.2 Post-market reviews

Table 38 Medical device targeted reviews

	2016-17	2017-18
	July to June	
Post market reviews		
Reviews commenced – number of ARTG entries	396	620
Reviews completed – number of ARTG entries	239	568
Reviews on hand – number of ARTG entries	263	315

8.3.3 Medical device incident reports

A medical device incident is an event associated with the use or misuse of a medical device that resulted in, or could have resulted in (near-incident), serious injury, illness or death to 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 TGA promotes and encourages users to report but cannot enforce reporting by users.

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

Table 39 Number of medical device incident reports and processing times

	2016-17	2017-18
	July to June	
Device incident reports		
Reports received	4,896	5,348
Reports completed	4,918	4,653
Reports still in progress	380	283
Processing time		
Mean TGA processing time (days)	1	1
Median TGA processing time (days)	10	6
Percentage processed within target timeframe	95%	98%

Table 40 Medical device incident report outcomes[a]

	2016-17	2017-18
	July to June	
Incident report outcome		
Reviewed and used for trend analysis purposes	4,125	4,713
Reviewed, no further action required	279	252
Product recall	70	27
Recall for product correction	4	57
Hazard alert	22	41
Product notification	0	0
Safety alert	20	2
Product enhancement/improvement notice	1	0
Instructions for use amended	5	6
Referral for post-market review	82	139
Refer to another TGA Branch	39	51
Company warned	13	9
Product suspended from ARTG	0	0
Product cancelled from ARTG	1	2
Manufacturing process improvements	12	10
Quality system process improvements	0	2
Maintenance carried out by the hospital	0	0
Change to design	3	4
Not device related	16	3
Other	81	403

[a] Outcomes are not mutually exclusive.

8.3.4 Devices manufacturing

Table 41 Outcomes of Quality Management System (QMS) audits of Australian manufacturers

	2016-17	2017-18
	July to June	
QMS audits (Australia)		
Number of audits conducted	38	41
Satisfactory compliance (of completed audits)	71%	92%
Marginal compliance (of completed audits)	24%	8%
Unacceptable (of completed audits)	0%	0%
Close-out in Progress	5%	37%
Processing time		
Initial audits conducted within 3 months of application	57%	83%
Re-audits conducted within 6 months of due date	16%	46%

Table 42 Outcomes of QMS audits of overseas manufacturers

	2016-17	2017-18
	July to June	
QMS audits (overseas)		
Number of audits conducted	26	30
Satisfactory compliance (of completed audits)	92%	100%
Marginal compliance (of completed audits)	0%	0%
Unacceptable (of completed audits)	0%	0%
Close-out in Progress	8%	60%
Processing time		
Initial certification audits conducted within 6 months of application	80%	72%
Certification re-audits conducted within 6 months of due date	9%	42%

Table 43 Outcomes of MDSAP Program

	2016-17	2017-18
	July to June	
MDSAP Assessments (overseas)		
Number of auditing organisation assessments	5	8
Number of witnessed manufacturing audits	4	5

9. Exports

9.1. Export only medicines

The target timeframe for processing of export only medicine applications and variations is 31 working days.

Table 44 Approval times for export only medicines

	2016-17	2017-18
	July to June	
New applications		
Mean TGA processing time (days)	25	25
Median TGA processing time (days)	26	26
Percentage processed within target processing time	75%	70%
Variations		
Mean TGA processing time (days)	22	19
Median TGA processing time (days)	22	23
Percentage processed within target processing time	89%	91%

Table 45 Applications for new and variations to export only medicines

	2016-17	2017-18
	July to June	
Export only applications		
Applications received	242	254
Applications awaiting response from sponsor	9	14
Applications completed		
Approved	207	237
Withdrawn	17	19
Total completed	224	256

9.2. Export certifications for medicines

The target processing time for applications for an export certificate for a medicine is 15 working days.

Table 46 Export certification applications and processing times

	2016-17	2017-18
	July to June	
Applications received	1,582	1,799
Applications completed		
Approved	1,413	1,849
Withdrawn	3	30
Total completed	1,416	1,819
Processing times		
Mean TGA processing time (days)	12	14
Median TGA processing time (days)	13	13
Percentage processed within target time	99%	69%

9.3. Export certification assessment for medical devices

The target processing time for applications for an export certificate for a medical device is 10 working days.

Table 47 Medical device applications and processing times for export certification assessments

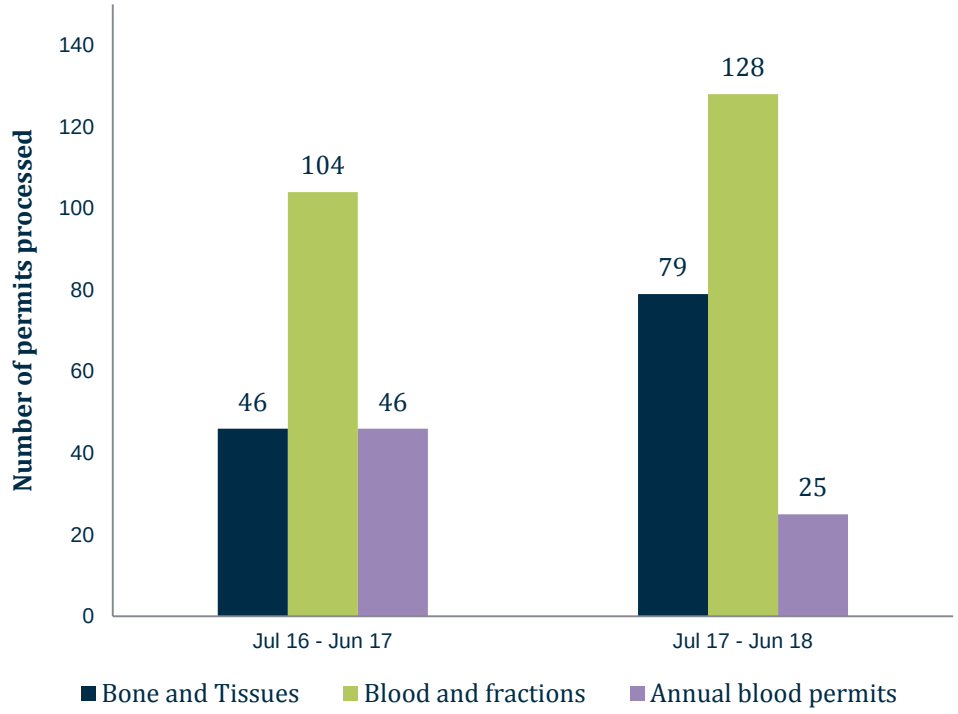
	2016-17	2017-18
	July to June	
Applications received	553	625
Applications completed		
Export certificates issued	504	617
Applications withdrawn	10	4
Total completed	514	621
Processing time		
Mean TGA processing time (days)	4.5	8
Median TGA processing time (days)	4	6
Percentage processed within target time	83%	80%

9.4. Blood permits for export

We issue permits to export human blood and its fractions (products derived from human blood) on receiving written applications from medical professionals, hospitals and bone banks. Most often these professionals or health organisations approach the Australian Red Cross Blood Service which then applies for the permit on their behalf. Very rarely an individual citizen may also apply with reference to his/her requirement, for example, a patient travelling overseas with Biostate® injections, which is a blood fraction and requires a permit to take it out of Australia.

In addition to issuing individual permits, the TGA also issues annual permits. Applications for these permits are submitted by commercial (pharmaceutical companies) or government organisations (such as the Australian Defence Force). The permits cover one year's worth of anticipated export supplies for these organisations.

Figure 7 Number of blood permits processed



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 (two pre-existing and one newly added pathway) 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 that do not fit the Category A definition. An approval letter from 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 48 SAS medicine notifications and applications

	2016-17	2017-18
	July to June	
Category A notifications		
Total Category A notifications	46,678	36,881
Category B applications		
Approved	21,609	11,641
Cancelled	355	40
Rejected	21	28
Pending at end of reporting period	418	370
Total Category B applications	22,403	12,079
Category C notifications		
Total Category C notifications	N/A	14,560
Total SAS notifications/applications received (all categories)	69,081	63,250

Table 49 SAS device notifications and applications

	2016-17	2017-18
	July to June	
Category A notifications		
Total Category A notifications	4,914	4,511
Category B applications		
Approved	2,113	2,466
Cancelled	96	15
Rejected	1	9
Pending at end of reporting period	135	143
Total Category B applications	2,345	2,633
Category C notifications		
Total Category C notifications	N/A	177
Total SAS notifications/applications received (all categories)	7,259	7,321

Table 50 SAS biological notifications and applications

	2016-17	2017-18
	July to June	
Category A notifications		
Total Category A notifications	47	110
Category B applications		
Approved	2,024	711[a]
Cancelled	89	8
Rejected	0	0
Pending at end of reporting period	44	9
Total Category B applications	2,157	728
Category C notifications		
Total Category C notifications	N/A	802
Total SAS notifications/applications received (all categories)	2,204	1,640

[a] Alternative products available on the ARTG.

10.2. Clinical trials

The Clinical Trial Notifications (CTN) scheme provides an avenue through which unapproved therapeutic goods may be lawfully supplied for use solely for experimental purposes in humans. Unapproved therapeutic goods can include biologicals, devices or medicines or a combination of any of the three types of goods.

Table 51 Number of notifications for new clinical trials involving unapproved therapeutic goods received by therapeutic good type

	2016-17	2017-18
	July to June	
Therapeutic good type		
Medicine	409	436
Device[a]	152	143
Biological	10	7
Medicine and device	290	325
Device and biological	1	1
Medicine and biological	6	5
Medicine, device and biological	0	3
Total	868	920

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

Table 52 Number of new clinical trial notifications involving unapproved therapeutic goods received by phase

	2016-17	2017-18
	July to June	
Clinical trial type		
Phase 1	191	262
Phase 2	189	209
Phase 3	257	246
Phase 4	89	65
Device	118	125
Bioavailability/equivalence	24	13
Total	868	920

Table 53 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

	2016-17	2017-18
	July to June	
Therapeutic good type		
Medicine	1,230	1,154
Device[a]	266	240
Biological	12	12
Medicine and device	1,417	1,557
Device and biological	2	5
Medicine and biological	10	11
Medicine, device and biological	1	4
Total	2,938	2,983

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

	2016-17	2017-18
	July to June	
Phases		
Phase 1	459	612
Phase 2	648	707
Phase 3	1,358	1,280
Phase 4	246	165
Device	194	195
Bioavailability/equivalence	33	24
Total	2,938	2,983

[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 55 Authorised Prescriber approvals for medicines, medical devices and biologicals

	2016-17	2017-18
	July to June	
Approvals by therapeutic good type		
Number of approvals for medicines	764	605
Number of approvals for medical devices	304	407
Number of approvals for biologicals	1	0
Total	1,069	1,012

11. Medicines and biologicals manufacturing

11.1. Manufacturing licences issued to Australian manufacturers

Table 56 Status of manufacturing licence applications

	2016-17	2017-18
	July to June	
Licence status (Australia)		
New licences granted	9	23
Withdrawn application	10	5
Revoked licences – at request of licence holder	19	19
Revoked licences – TGA	1	2
Suspended – at request of licence holder	1	2
Suspended – TGA	0	0

As at 30 June 2018, there were 248 Australian companies holding manufacturing licences covering 393 sites.

Table 57 Outcomes of inspections of Australian manufacturers[a]

	2016-17	2017-18
	July to June	
Inspection status (Australia)		
Number of inspections conducted	185	210
Satisfactory compliance (of completed inspections)[b]	88%	85%
Marginal compliance (of completed inspections)[c]	10%	10%
Unacceptable (of completed inspections)	2%	5%
Close-out in progress	18%	9%
Processing time		
Initial inspections conducted within 3 months of application	85%	96%
Re-inspections conducted within 6 months of due date	61%	72%

[a] For a description of compliance ratings refer to https://www.tga.gov.au/manufacturer-compliance-history.

[b] Satisfactory Compliance reflects the A1 and A2 manufacturers.

[c] Marginal Compliance reflects the A3 manufacturers.

11.2. Approval (certification) of overseas manufacturers

Table 58[a] Manufacturing certification application by status (overseas)

	2016-17	2017-18
	July to June	
Applications (overseas)		
New applications received	46	33
Re-inspection applications	38	55[a]
Applications completed		
Certified	33	85[a]
Rejected[b]	59	51
Total completed	92	136

[a] For the period 2017-18 the table above will now include TGA created certification applications.

[b] Rejections include withdrawn applications.

As at 30 June 2018, there were 208 overseas manufacturers covering 211 manufacturing sites that were subject to TGA inspection and approximately 2,700 overseas manufacturing sites that relied on evidence from recognised regulators.

Table 59 Outcomes of inspections of overseas manufacturers[a]

	2016-17	2017-18
	July to June	
Inspection status (overseas)		
Number of inspections conducted	58	84
Satisfactory compliance (of completed inspections)[b]	94%	86%
Marginal compliance (of completed inspections)[c]	6%	11%
Unacceptable (of completed inspections)	0%	3%
Close-out in progress	10%	12%
Processing time		
Initial certification inspections conducted within 6 months of application	64%	68%
Certification re-inspections conducted within 6 months of due date	66%	66%

[a] For a description of compliance ratings refer to https://www.tga.gov.au/manufacturer-compliance-history.

[b] Satisfactory Compliance reflects the A1 and A2 manufacturers.

[c] Marginal Compliance reflects the A3 manufacturers.

11.3. Good Manufacturing Practice clearances

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

Table 60 GMP clearance application status

	2016-17	2017-18
	July to June	
Applications received	5,471[a]	5,327
Applications completed		
Approved	5,067	5,041
Rejected	642	344
Total completed	5,709	5,385

[a] For the financial year 2016-17 the number of applications received has been adjusted to reflect the actual number of submitted and paid applications.

12. Recalls

12.1. Medicine recalls

Table 61 Medicine recalls by reason for recall

	2016-17	2017-18
	July to June	
Reason for recall		
Adverse reactions	1	1
Foreign matter	3	5
Illegal supply	0	2
Impurity and degradation	3	1
Labelling and packaging	7	8
Micro-organisms	2	1
pH	0	0
Potency	3	3
Sterility	0	1
Other[a]	13	13
Total	32	35

[a] 'Other' includes dissolution, physical defects, observed differences, variable content, diagnostic inaccuracy and wrong product, disintegration/dissolution, GMP non-compliance and transport/storage.

12.2. Medical device recalls

Table 62 Medical device (including IVDs) recalls by reason for recall

	2016-17	2017-18
	July to June	
Reason for recall		
Adverse incidents	7	3
Diagnostic inaccuracy	105	3
Electrical defect	28	41
Illegal supply	2	2
Labelling and packaging	89	14
Mechanical and physical defects	169	202
Software defects	109	97
Sterility	14	5
Other[a]	75	187
Total	598	554

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

12.3. Biological recalls

Table 63 Biological recalls

	2016-17	2017-18
	July to June	
Recalls to hospital level	2	25[a]

a. There has been a large proportional increase in the recall of biological products. This may be attributed to increased stakeholder awareness of the overall regulatory framework for this product category.

13. Laboratory testing

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

Our Laboratories Branch identifies and prioritises therapeutic goods for testing to fulfil the regulatory compliance and monitoring requirements of the TGA, 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 is used, which is consistent with *ISO 31000: Risk Management principals and guidelines,* 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.

We continue to publish laboratory results through the *Database of TGA Laboratory Testing Results*[1]. 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. 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.

On 8 September 2017 the Pacific Medicines Testing Program was launched. This is a joint program between the Department of Foreign Affairs and Trade and the Therapeutic Goods Administration. Under the Program the TGA Laboratories will test the quality of five medicines per Pacific Island Country per year (2017-2021). The focus of the Program is medicines for non-communicable diseases, such as high blood pressure and diabetes, as well as antibiotics and medicines purchased in high volumes.

[1] https://www.tga.gov.au/ws-labs-index

Table 64 Samples and products tested by type of therapeutic good and percentage which failed

		2016-17	2017-18
		July to June	
Therapeutic good type			
Prescription medicines	Total	1,168	1,106
	% fail	0.9	0.5
OTC medicines[a]	Total	51	59
	% fail	13.7	6.8
Complementary medicines[a]	Total	87	266
	% fail	13.8	10.2
Medical devices	Total	168	99
	% fail	31	41.4
External[b]	Total	32	70
	% fail	62.5	8.6
Pacific Medicines Testing Program	Total	N/A	21
	% Fail	N/A	14.3
Unregistered[c]	Total	220	155
	% fail	63.6	56.1
Total samples (excluding AHQ samples)		1,726	1,776
Total samples[d]		2,328	2,005
Percentage fail		14%	10%
Total number of products tested[e]		590	836

[a] Listed medicines tested by the Laboratories Branch are included in either the OTC or Complementary Medicines figures.

[b] Performed on request for overseas regulators or aid agencies and encompasses medicines and medical devices.

[c] '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.

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

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

Table 65 Samples that failed laboratory testing by reason for July 2017 to June 2018

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Complementary medicines	External	Pacific Medicines Testing Program	Total
Contamination	2	0	1	0	2	0	0	5
Formulation	0	1	0	86	14	5	3	109
Label and packaging deficiencies	23	0	3	1	8	0	0	35
Performance	13	0	0	0	2	0	0	15
Physical or mechanical properties	3	3	2	0	1	1	0	10
Unregistered	0	0	0	0	0	0	0	0
Total	41	4	6	87	27	6	3	174

Table 66 Batch release and export certification

	2016-17	2017-18
	July to June	
Batch releases and certifications		
Batch release[a]	453	432
Export certification[b]	75	34

[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 Laboratories Branch provides WHO-approved certificates for batches of biological products to be exported by Australian manufacturers to overseas markets. The number of certificates provided by the Laboratories Branch therefore depends on the number of requests received.

Table 67 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 68 Compliance with testing timeframes[b] for July 2017 to June 2018

	Priority	Total	Percentage
Therapeutic good type[a]			
Medical devices	Routine	55	87.3
	Priority	44	70.5
	Urgent	0	N/A
OTC medicines	Routine	54	33.3
	Priority	5	80
	Urgent	0	N/A
Prescription medicines	Routine	225	43.6
	Priority	24	100
	Urgent	2	100
Complementary medicines[c]	Routine	219	43.8
	Priority	47	70.2
	Urgent	0	N/A
Unregistered products	Routine	1	100
	Priority	149	84.6
	Urgent	5	100

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

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

[c] Listed medicines tested by the Laboratories Branch are included in either the OTC or Complementary Medicines figures.

14. Regulatory compliance

Our regulatory compliance and investigations area 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 intended purpose of protecting public health.

Table 69 Regulatory compliance investigations by final action taken

	2016-17	2017-18
	July to June	
Investigations in progress	1,136	1,013
Completed investigations		
Warned (including destruction)	1,973	2,173
No offence detected	110	226
Goods released under Personal Import Scheme	691	324
Referred to another agency or department outside Health	21	58
Referred to another branch within the TGA	13	28
Filed for intelligence purposes	45	161
Finalised in a linked file	25	5
Import treated as abandoned goods by Customs	8	5
Recall of goods	1	0
Matters referred to the Commonwealth Director of Public Prosecutions	0	2
Total completed	2,887	2,982
Units seized and destroyed at the point of importation[a]	884,081	850,514

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

Table 70 Types of products investigated[a]

	2016-17	2017-18
	July to June	
Therapeutic good type		
Complementary medicines	599	294
Prescription medicines	4,367	5,214
Medical devices	166	131
Homoeopathic medicines	36	550
OTC medicines	54	71
Biological products	28	31
Other[b]	119	91
Total	5,369	6,382

[a] Regulatory compliance investigations may include more than one type of product.

[b] Includes unidentifiable and Schedule 8, 9 and 10 products.

Table 71 Regulatory compliance investigations by special interest categories

	2016-17	2017-18
	July to June	
Compliance investigation category		
Unapproved product	4,855	6,497
Counterfeit product	326	218
Parallel import/export	28	1
Manufacture without licence	8	3
Traditional Chinese medicines	15	20
Other[a]	33	8
Total	5,265	6,747

[a] Products that fall outside the remit of the *Therapeutic Goods Act 1989,* for example food products, cosmetics and raw starting materials.

Table 72 Location of alleged offence by referral type for July 2017 to June 2018

Origin	ACT	NSW	NT	QLD	SA	VIC	WA	TAS	Total
Complaints resolution Panel	0	2	0	0	0	2	1	0	5
Australia Border Force / Customs	48	819	136	604	326	1,178	289	69	3,469
External Agencies, Other Regulatory Body, State Health Body	2	17	0	16	1	8	4	0	48
General public	1	81	1	46	8	41	19	0	197
Sponsor/client, Patient /Practitioner	2	32	1	9	2	15	6	0	67
TGA internal	1	30	1	18	4	7	4	2	67
Total	54	981	139	693	341	1,251	323	71	3,853

15. Pharmacovigilance Inspection Program

Table 73 PVIP inspections undertaken and deficiencies identified

	2017-18
	July to June[a]
Total completed	5
Total with completed findings	4
Critical deficiencies[b]	0
Major deficiencies[c]	21
Minor deficiencies[d]	10
Average deficiencies per inspection	5 major 3 minor

[a] Inspections commenced in January 2018.

[b] 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.

[c] 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.

[d] 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.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Reporting and Collaboration Services	27/09/2018

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