



Australian Government

Department of Health

Therapeutic Goods Administration

Therapeutic Goods Administration Half Yearly Performance Snapshot

1 July to 31 December 2017



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Introduction

The Therapeutic Goods Administration (TGA) prepares an annual *TGA Business Plan*, which identifies the priority activities being undertaken over the 2017-18 reporting period and is available on the TGA website. This *Half Yearly Performance Snapshot* provides statistical information for 1 July to 31 December 2017 in relation to our regulation of therapeutic goods for safety, effectiveness, performance and quality, tracking our progress against the priorities we have identified for the year.

As part of our annual plan we have been working to implement the Government's response to the Review of Medicines and Medical Devices Regulation. Following the passage of amendments to the Therapeutic Goods Regulations through the Therapeutic Goods Amendment (2016 Measures No. 1) Bill, this reporting period now includes new data sets¹ in relation to:

- Orphan Drugs
- Special Access Scheme
- Authorised Prescriber Scheme and
- Priority pathways for medicines and medical devices.

Further information about how therapeutic goods are regulated in Australia can be found on the TGA website.

Performance highlights

The TGA has maintained a high level of activity while also progressing regulatory reforms over the reporting period, 1 July to 31 December 2017. Highlights are as follows:

Regulatory reforms

Orphan drug program reform

- A 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 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

- The Special Access Scheme (SAS) Category C notification pathway was made available on 3 July 2017 to increase timeliness and ease access to therapeutic goods for Australian patients. This pathway allows certain unapproved goods when used for a particular indication to be supplied immediately to patients by an authorised health practitioner without first requiring approval by the TGA. A total of 4,975 notifications for access to therapeutic goods were received under the new SAS Category C notification pathway.

¹ Tables 2, 3 and 5

Authorised Prescriber Scheme

- From 3 July 2017, changes were made to the Authorised Prescriber Scheme to streamline the application process by removing the requirement for doctors to submit clinical justification with their application.

Priority review of prescription medicines

- A new priority review pathway was 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 TGA's high standard for efficacy, safety and quality.

Priority review of medical devices

- Priority review of certain novel medical devices commenced from January 2018. Priority review designation is for breakthrough technologies treating life threatening or seriously debilitating conditions where there is unmet clinical need. Applications which are granted a Priority review designation will be allocated 'front-of-queue' priority throughout the relevant assessment process (whether that is for conformity assessment and/or inclusion on the Australian Register of Therapeutic Goods (ARTG)).

Medicines

Prescription medicines

- Over the reporting period, 166 Category 1 (including 22 New Chemical Entities (NCE) and 55 new generic medicines) and 695 Category 3 applications were approved. This represents an increase against the equivalent period in 2016 (156 Category 1 and 665 Category 3 applications). Mean and median approval times were below the statutory timeframes.
- Mean and median approval times for new generic medicines (190 and 185 working days respectively) and Product Information changes (130 and 129 working days respectively) were below that of NCE (209 and 212 working days respectively) as these application types are typically processed without referral to independent expert advisory committees.

Over-the-counter medicines

- The number of new medicine applications (N1 to N5) and applications to change existing medicines (C2 to C4) approved in July to December 2017 (300) was higher than for the equivalent period in 2016 (206). Despite the increase in numbers for these application types, the percentages of applications completed within target timeframes were well above the 80% target (93% for N4 applications and 100% for all other application types).

Complementary medicines

- In line with the increase in the proportion of medicines which were cancelled by a sponsor after our request for information (73%, compared with 20% for July to December 2016), and the increase in the number of targeted reviews in recent years, the proportion of medicines with verified compliance breaches decreased to 56% (compared with 80% for July to December 2016).

Medical devices

- There was a 69% increase in the number of completed new medical device conformity assessments (44, compared with 26 for July to December 2016) and a 39% increase in changes or recertification (88, compared with 63 for July to December 2016).
- There was also a significant increase in applications for Class 1 medical devices and in vitro devices (IVDs) on the ARTG (1,545, compared with 1,209 for July to December 2016).

Licensing and manufacturing

- There was a significant increase in inspections conducted in this period of Australian manufacturers (96, compared with 74 in the equivalent period in 2016) and overseas manufacturers (49, compared with 30 in the equivalent period in 2016). This was due to a combination of factors including increased inspection resources, and performing more inspections with shorter inspection duration.
- Initial inspections conducted for Australian manufacturers within 3 months of application increased from 75% to 92% when compared with the equivalent period in 2016. This improvement was achieved by ensuring initial inspections were conducted in a timely manner.

Access to unapproved therapeutic goods

Clinical trials

- Consultations on the updated Australian Clinical Trials Handbook were completed. This document is being updated to reflect current practice and improve consistency in guidance documents between the TGA and the National Health and Medical Research Council. Online portal functionality was improved for Sponsors and a total of 481 new Clinical Trial Notifications were received.

Medicine and vaccine adverse event reports

- We have been working closely with state and territory health departments to monitor the safety of vaccines included in the National Immunisation Program. This work is reflected in the increase in the number of Adverse Drug Reaction Reports related to vaccines submitted by state and territory health departments.

Regulatory compliance

- A new case prioritisation model and improved process was implemented for the assessment of referrals for compliance or investigative action. This, along with improved information on target imports, has strengthened our relationship with the Australian Border Force. Consequently, there has been a substantial increase in compliance actions during the period (1,530, compared with 789 in July to December 2016), including 363,763 units of imported therapeutic goods destroyed as being non-compliant with the regulatory framework.

Recalls

- Analysis of outcomes for blood-related recalls for the previous ten reporting periods shows activity is now lower than previous levels. Outcomes for medicine and medical device-related recalls have remained relatively consistent when compared with previous reporting periods.

Processing and approval times

Processing and approval times are defined as the number of working days from the acceptance of the application until formal notification of decision, unless otherwise specified. These exclude times where we were unable to progress the application until the sponsor provides additional information or payment of fees, unless otherwise specified. Under the *Therapeutic Goods Act 1989* (the Act), TGA working days exclude public holidays and weekends.

1. Prescription medicines

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

- **Category 1 application:** an application to register a new prescription medicine 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.
- **Category 2 application:** an application accompanied by two independent evaluation reports from comparable overseas regulators in whose jurisdiction the product is approved for the same indication.
- **Category 3 application:** 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, a change in the site of manufacture, a change to the synthetic route, a change in the product specifications, a change in the steps of manufacture or a change in trade name.

Figure 1: Number of approved Category 1 submissions by type for July to December 2017

Prescription medicine submissions may include a number of applications submitted at the one time. The data presented below relates to the number of submissions as this best reflects the evaluation and decision-making processes.

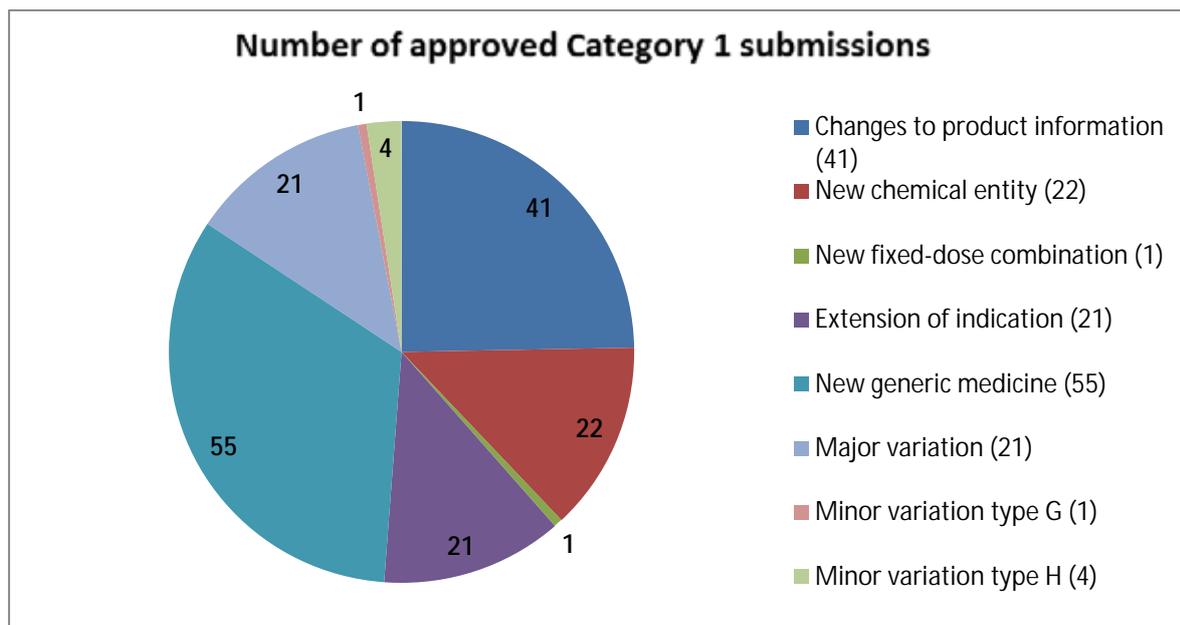


Table 1 Prescription medicine application approval time for July to December 2017

			Approval time (TGA working days)		
Application type	Submissions approved	Legislated timeframe	Mean	Median	Range
A: New chemical entity/New biological entity/biosimilar					
Category 1	22	255	209	212	152-245
B: New fixed-dose combination					
Category 1	1	255	178	178	178-178
C: Extension of indication					
Category 1	21	255	183	189	85-223
D: New generic medicine					
Category 1	55	255	190	185	123-254
E: Additional trade name (ATN)					
ATN	41	45	25	27	4-43
F: Major variation					
Category 1	21	255	195	196	155-254
G: Minor variation ^a					
Category 1	1	255	250	250	250-250
Category 3	51	45	37	40	3-45
H: Minor variation ^b					
Category 1	4	255	167	168	161-171
Category 3	644	45	32	33	4-59
J: Changes to product information requiring the evaluation of data					
Category 1	41	255	130	129	7-242

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) included in the table above 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.

Table 2 Priority review determinations granted for July to December 2017

A prescription medicine must have a valid priority review determination before it can be evaluated for registration under the priority review pathway. Since the introduction of the new pathway, eight priority review determinations have been granted.

Priority Review Applications	
Application Type	Approved
A: New chemical entity/New biological entity	2
C: Extension of Indications	6

Table 3 Orphan Drug Designations granted for July to December 2017 under the new eligibility criteria

A prescription medicine must have a valid orphan drug designation to be eligible for the benefit of designation, and a waiver of application and evaluation fees. Since the introduction of the new regulations, five orphan drug designations have been granted. Reporting on orphan drugs reflects only those submitted through the new scheme.

Orphan Drug Applications	
Application Type	Approved
A: New chemical entity/New biological entity/Fixed dose combination	3
C: Extension of Indications	1
F: Major Variation	1

2. Over-the-Counter medicines

Over-the-Counter (OTC) medicine applications are categorised as new medicine (N) or change (C) applications and are further categorised by risk (N1 and C1 are lowest risk, N5 and C4 are highest risk).

Application category	Definition
N1	An application submitted as a 'Clone'.
N2	An application which complies with an OTC medicine monograph.
N3	New application for a 'generic' medicine other than those 'generic' applications in levels N1, N2 or N4.
N4	An application for a 'generic' medicine where the medicine: <ul style="list-style-type: none"> 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.
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.
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'.
C1	Quality and non-quality changes classified as 'negligible risk'.
C2	Quality and non-quality changes classified as 'low risk' – no safety and/or efficacy data required; quality data may be required.
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.
C4	Non-quality changes classified as 'moderate risk' – safety and/or efficacy data required unless justified.
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.

Table 4 Over-the-Counter medicine application processing time for approved applications for July to December 2017

	Total approved	Target approval time (days)	Mean	Median	Range	Percentage within target
New medicine applications						
N1 Lower risk	89	45	20	20	0-40	100
N2	3	55	38	39	35-39	100
N3	16	150	74	74	0-129	100
N4	14	170	81	52	0-204	93
N5 Higher risk	4	210	156	154	152-162	100
Change applications						
C1 Lower risk	110	20	4	3	0-18	100
C2	167	64	24	23	0-61	100
C3	3	120	35	20	12-72	100
C4 Higher risk	4	170	99	95	46-159	100

Table 5 Other over-the-counter medicine applications

Application type	Approved	Rejected	Total
Change Notifications (CN)	83	N/A ^a	83
Requests for consent under section 14/14A of the Act	5	0	5

^a Automated validation and approval

3. Complementary medicines

3.1. Registered complementary medicines

Table 6 Number of approved registered complementary medicine applications

	Jul – Dec 2016	Jul – Dec 2017
New registered medicines	4	1
Variation to registered medicines	11	7

3.2. Listed complementary medicines

Table 7 Number of new ingredients permitted for use in listed medicines

	Jul – Dec 2016	Jul – Dec 2017
New permitted ingredients	50	42

Table 8 Number of new listed medicines

	Jul – Dec 2016	Jul – Dec 2017
New listed medicines	754	916

Table 9 Number of listed medicine reviews by type

	Jul – Dec 2016	Jul – Dec 2017
Reviews initiated		
Random reviews	0	90
Targeted reviews	235	29
Total	235	119
Reviews completed		
Random reviews	83	32
Targeted reviews	168	86
Total	251	118

Table 10 Number of completed listed medicine reviews by outcome

	Jul – Dec 2016	Jul – Dec 2017
Compliance status determined		
Medicines with no compliance breaches	43	37
Medicines with verified compliance breaches	167	45 ^a
Sub-total	210	82
Compliance status unable to be determined		
Medicines cancelled by sponsors after request for information	8	24
Medicines not yet manufactured or information unavailable	33	6
Other	0	3
Sub-total	41	33
Product not a therapeutic good	0	3
Total completed	251	118

a During the July to December 2017 reporting period there was a strong focus on sunscreens.

4. Biologicals

Table 11 Number of completed biological applications

Blood, blood components, plasma derivatives, tissue and cellular products, tissue and cell based derivatives, and other emerging biological therapies are regulated under the *Therapeutic Goods Act 1989*.

	Jul – Dec 2016	Jul – Dec 2017
Technical Master File (TMF) new	1	0
TMF annual updates	5	1
TMF variations	7	6
TMF notifications	7	4
Plasma Master File annual updates	8	7
Biological Class 2 – new applications	0	0
Biological Class 3 – new applications	1	2
Biological Class 2 – variations	10	1
Biological Class 3 – variations	0	1
Total completed	39	22

5. Medical devices

The regulatory framework for medical devices spans the life cycle of these products, including conformity assessment, inclusion on the ARTG and post-market monitoring.

Table 12 Number of completed applications and processing time for conformity assessments of medical devices (including in vitro diagnostic medical devices (IVDs))

	Jul – Dec 2016	Jul – Dec 2017
New devices		
Total completed	29	44
Percentage processed within target processing timeframes	100%	100%
Mean TGA processing time (working days)	118	128
Median TGA processing time (working days)	133	183
Changes to recertification		
Total completed	63	88
Percentage processed within target processing timeframes	100%	100%
Mean TGA processing time (working days)	100	115
Median TGA processing time (working days)	76	115

Note: The TGA is required to complete conformity assessment applications within 255 working days.

Table 13 Number of completed applications for inclusion of medical devices and IVDs on the ARTG

	Jul – Dec 2016	Jul – Dec 2017
Class I medical devices	1,209	1,545
Class I measuring medical devices	25	22
Class I sterile medical devices	136	127
Class IIa medical devices	642	607
Class IIb medical devices	345	328
Class III medical devices	228	189
Class III Joint Reclassification medical devices	114	63
Active Implantable Medical Devices (AIMD)	56	28
Class 1 IVDs	41	45
Class 2 IVDs	38	47
Class 3 IVDs	21	19
Class 4 IVDs	6	10

Table 14 Number of application audits completed and processing time for medical devices and IVDs for July to December 2017

	Total completed	Processing times	
		Mean	Median
Medical devices			
Auto-included applications ^a	1,545		
Applications completed without audit ^b	1,049	4	3
Non-compulsory audits ^c	116	59	23
Level 1 compulsory audits	9	37	18
Level 2 compulsory audits	190	94	56
IVDs			
Auto-included applications ^a	40		
Applications completed without audit ^b	59	4	2
IVD non-compulsory audit	3	14	17
IVD compulsory audit	19	50	52

a Class I and Class 1 IVDs (with some exception) are automatically included medical devices and are not subject to audits before inclusion. Separate post-market monitoring is undertaken for these goods.

b These figures do not include applications for Class I and Class 1 IVD auto-included devices. These applications are completed within 20 working days.

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), and applications supported by European Community certificates issued by certain notified bodies (for details see [Increased application audit requirements for some medical devices applications](#)).

6. Exports

Table 15 Number of approved applications for export-only medicines and export certifications and relevant processing time for July to December 2017

	Total Approved	Target processing time (days)	Processing Time	
			Mean	Median
Export-only medicines				
New application	70	30	20	20
Variation	49	30	19	21
Export certificates				
Medicine applications	928	15	12	12
Medical device assessments	354	10	6	6

7. Access to unapproved therapeutic goods

7.1. Special Access Scheme

Table 16 Number of completed applications and notifications for the Special Access Scheme

	Jul – Dec 2016	Jul – Dec 2017
Medicines		
Category A	20,194	16,824
Category B	10,377	5,968
Category C	N/A ^a	4,732
Medical devices		
Category A	2,832	2,014
Category B	979	1,692
Category C	N/A ^a	1
Biologicals		
Category A	6	22
Category B	1,091	371
Category C	N/A ^a	242

^a The Category C pathway was introduced on 3 July 2017.

7.2. Authorised prescribers

Table 17 Number of authorised prescriber approvals for medicines and medical devices

	Jul – Dec 2016	Jul – Dec 2017
Medicines	391	355
Medical devices	177	114

7.3. Clinical trials

Table 18 Number of notifications for new clinical trials received by therapeutic good type for July to December 2017

	Jul – Dec 2016	Jul – Dec 2017
Medicine only	197	223
Medical device only	71	77
Biological only	3	4
Medicine and medical device	127	171
Medical device and biological	1	1
Medicine and biological	11	2
Medicine, medical device and biological	7	3
Total	417	481

Table 19 Number of notifications for new clinical trials received by phases for July to December 2017

	Jul – Dec 2016	Jul – Dec 2017
Phase 1	72	120
Phase 1 and 2 in combination	11	24
Phase 2	82	89
Phase 2 and 3 in combination	4	6
Phase 3	113	126
Phase 4	41	32
Bioavailability / equivalence	13	5
Other phases in combination	25	5
Device only	56	74

Note: A trial may be notified with more than one phase type.

8. Licensing and manufacturing

Number of manufacturing inspections by outcome

Table 20A Medicines and Blood, Tissue and Cellular Therapies

	Jul – Dec 2016	Jul – Dec 2017
Outcomes of inspections of Australian manufacturers		
Number of inspections conducted	74	96
Satisfactory compliance (of completed inspections) ^a	82%	89%
Marginal compliance (of completed inspections) ^a	16%	10%
Unacceptable (of completed inspections) ^a	2%	1%
Close-out in progress	16%	11%
Processing time		
Initial inspections conducted within 3 months of application	75%	92%
Re-inspections conducted within 6 months of due date	70%	68%
Outcomes of inspections of overseas manufacturers		
Number of inspections conducted	30	49
Satisfactory compliance (of completed inspections) ^a	96%	83%
Marginal compliance (of completed inspections) ^a	4%	13%
Unacceptable (of completed inspections) ^a	0%	4%
Close-out in progress	17%	6%
Processing time		
Initial certification inspections conducted within 6 months of application	50%	53%
Certification re-inspections conducted within 6 months of due date	58%	60%

a Compliance data for this period is aligned with data reported for the 2016 Jul-Dec period and excludes 'Close-out in progress' in calculation of percentages i.e. the percentages reported are limited to those inspections that are completed.

Applicants often submit applications for GMP licences and certifications before finalising all of their systems and processes. TGA works with the applicant to ensure an inspection is not conducted before the manufacturing facility is ready. It is therefore not uncommon for inspections to be conducted later than the target dates.

Table 20B Medical Devices

	Jul – Dec 2016	Jul – Dec 2017
Quality Management System (QMS) Audits (domestic manufacturers)		
Number of audits conducted	18	22
Satisfactory compliance (of completed audits)	39%	17%
Marginal compliance (of completed audits)	22%	33%
Unacceptable (of completed audits)	0%	0%
Close-out in progress	39%	50%
Processing time		
Initial audits conducted within 3 months of application	33%	66%
Re-audits conducted within 6 months of due date	27%	56%
QMS Audits (overseas manufacturers)		
Number of audits conducted	13	12
Satisfactory compliance (of completed audits)	69%	17%
Marginal compliance (of completed audits)	0%	33%
Unacceptable (of completed audits)	0%	0%
Close-out in progress	31%	
Processing time		
Initial certification audits conducted within 6 months of application	43%	38%
Certification re-audits conducted within 6 months of due date	84%	50%

TGA receives applications for Conformity Assessment Certification and conducts assessment of these applications. It may be determined that an audit of one or more manufacturers included in the Conformity Assessment Application is required. The timeframes used below for calculation of conducted audits are from the date of notification of this requirement.

The implementation of the Medical Device Single Audit Program (MDSAP) has enabled a reduction in the overall number of internal on-site audits required, substituted by a desktop assessment based on the MDSAP audit report. For medical devices we completed:

- 42 desktop assessments for 2015-16 financial year
- 74 desktop assessments for 2016-17 financial year
- 34 desktop assessments were completed, and 31 remained in progress at 31 December 2018.

Table 21 Number of GMP clearance applications

GMP clearance is required for all medicines (unless exempt) supplied in Australia, including for products supplied to sponsors by overseas manufacturers.

	Jul – Dec 2016	Jul – Dec 2017
Applications received	2,458	2,909
Applications completed		
Approved	2,619	2,780
Rejected	166	167
Total completed	2,785	2947

9. Laboratories

Table 22 Number of samples tested by type of therapeutic good and percentage which failed for July to December 2017

Product type	Jul – Dec 2016		Jul – Dec 2017	
	Total	% fail	Total	% fail
Prescription medicines	603	1%	482	1.0%
OTC medicines	30	23%	9	0.0%
Complementary medicines	41	22%	123	16%
Medical devices	112	30%	42	38%
Contract ^a	14	86%	31	16%
Unregistered ^b	97	64%	109	51%
Total samples (excluding AHQ samples) ^c	897	15%	796	13%
Total samples (including AHQ samples) ^c	1,229	11%	915	11%
Total number of products tested ^d	325	-	415	-

a Performed on request for overseas regulators or aid agencies 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 Accreditation, harmonisation and quality control (AHQ) samples.

d The TGA may test a number of samples of each product per reporting period.

10. Medicine and Vaccine Adverse Event Reporting

Table 23 Source of notifications of medicine and vaccine adverse reaction

	Jul – Dec 2016	Jul – Dec 2017
Reports with clear causality, by reporter		
Hospitals	919	808
Companies	4,952	4,916
General practitioners	270	262
Specialists	178	89
Pharmacists	489	544
Members of the public (consumers)	493	508
Nurses, dentists, complementary healthcare practitioners	74	94
State/Territory Health departments	1,264	1,485
Unregistered online reporters	64	10
Reports rejected or without clear causality		
	1,165	1,072
Total received	9,868	9,788
Mean number of reports received weekly	379	376
Vaccine reports included in this table	1,637	1,779

11. Medical device incident reports

Table 24 Number of completed medical device incident reports and processing time

Processing time is defined as the number of working days from receipt of the notification until the incident has been investigated and resolved.

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

	Jul – Dec 2016	Jul – Dec 2017
Reports completed	2,100	2,771
Mean TGA processing time	7	15
Percentage processed within target timeframe	94%	95%

12. Regulatory compliance

Data in relation to an investigation may appear in multiple tables as a compliance matter may be captured under several categories.

Table 25 Number of products investigated for compliance issues by product type

	Jul – Dec 2016	Jul – Dec 2017
Complementary and homeopathic medicines	247	335
Prescription medicines	1,748	1,528
Medical devices	46	108
OTC medicines	12	56
Biological products	14	12
Other	26	47
Total	2,093	2,086

Table 26 Number of completed regulatory compliance investigations by final action taken

	Jul – Dec 2016	Jul – Dec 2017
Warned ^a	449	1,101
No offence detected	20	61
Goods released under the Personal Importation Scheme	293	309
Referred to another agency or department outside Health	4	11
Referred to another Branch within the TGA	4	N/A ^b
Filed for intelligence purposes	12	41
Finalised in a linked file	6	3
Import treated as abandoned goods	0	1
Recall of goods	1	0
Matters referred to the Commonwealth Director of Public Prosecutions	0	3
Total completed	789	1,530

a The category 'warned' can include goods destroyed as prohibited imports and goods re-exported. In the period 870 certificates were issued for the destruction of 363,763 units.

b The category 'referred to another Branch within the TGA' is no longer being included in this report.

Table 27 Number of regulatory compliance investigations by offence category

	Jul – Dec 2016	Jul – Dec 2017
Import	1,434	1,669
Supply	66	178
Claims	5	10
Manufacture	5	4
Export	2	2
Forgery	1	0
Total completed	1,513	1,863

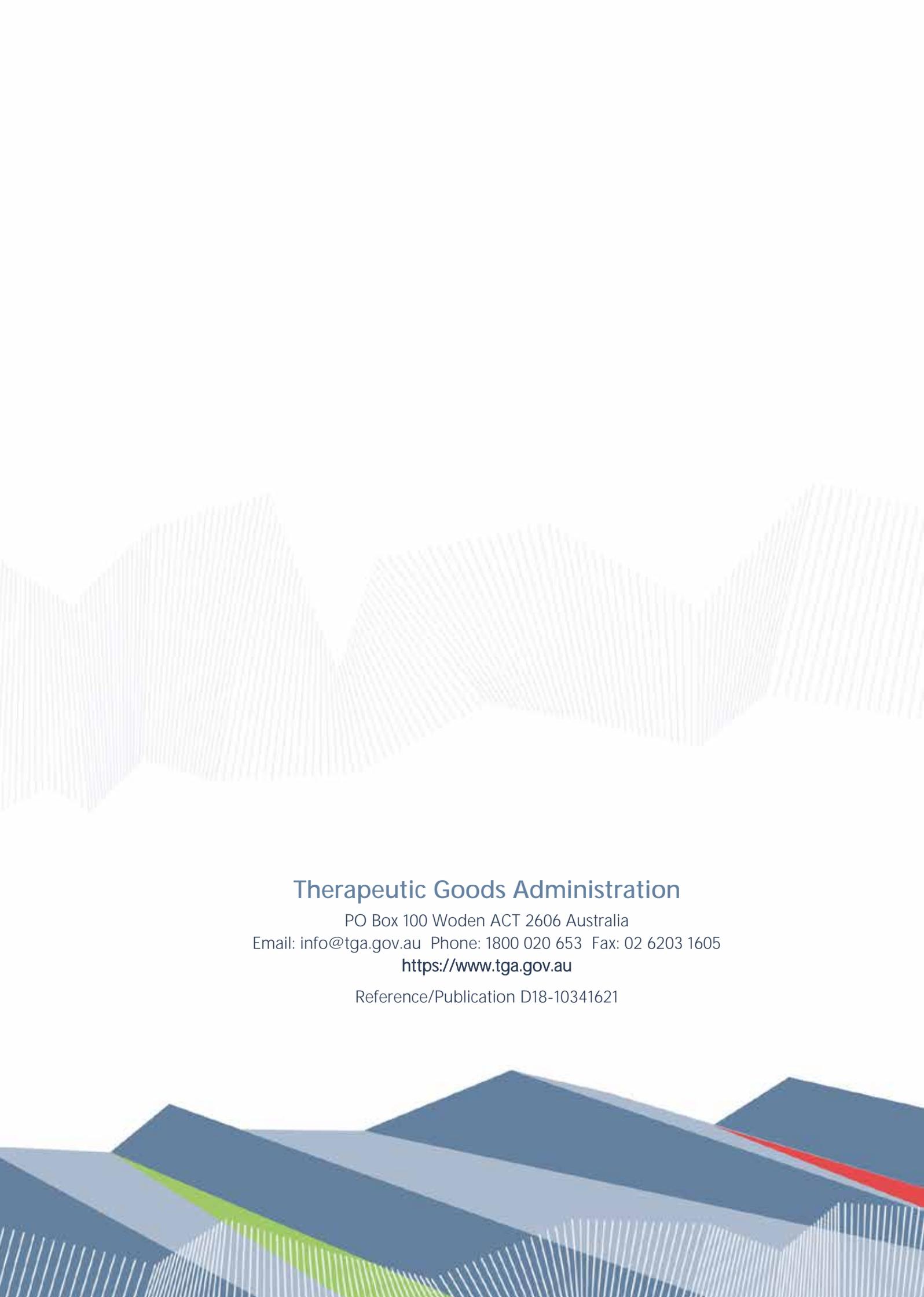
13. Recalls

Table 28 Number of therapeutic goods recalls

	Jul – Dec 2016	Jul – Dec 2017
Medicines	16	21
Medical devices (including IVDs)	301	284
Biologicals	2	0
Bloods	55	38
Total recalls	374	343

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Reporting and Collaboration Services	03/04/2018



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<https://www.tga.gov.au>

Reference/Publication D18-10341621