Australian Government
Department of Health
Therapeutic Goods Administration

Half yearly performance report

January to June 2015

Version 1.0, December 2015

TGA Health Safety Regulation

About the TGA

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for ensuring that therapeutic goods available for supply in or exported from Australia are safe and fit for their intended purpose. We regulate the import, supply, export, manufacture and advertising of therapeutic goods including:

- medicines: prescription and over-the-counter medicines, vaccines, complementary medicines, and blood and plasma products
- medical devices: which includes a wide variety of products ranging from lower risk items like adhesive bandages through to higher risk devices like pacemakers
- biologicals: stem cells, tissues and cell based products.

For more information about the type of products we regulate, and how the regulatory system works, please visit the TGA basics section of our website.

The half yearly performance report

This half yearly performance report covers the period 1 January to 30 June 2015 inclusive.

Future reports will be published annually, with the next report covering July 2015 to June 2016. This is in line with the report against the *TGA key performance indicators and measures: Regulator Performance Framework*.

The KPI report outlines performance against our broad strategic intent, and should be read in conjunction with the performance statistics provided in the future copies of this report.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Reporting and Collaborative Services	December 2015

Contents

1 Prescription medicines

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

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 (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.
- Examples of Category 1 applications include new chemical entities, extensions of indication, and new routes of administration. The legislated timeframes for the two stages of a Category 1 application are: 40 working days for notification of acceptance or rejection of the application and 255 working days for the completion of the evaluation and notification of the decision.
- **Category 2 application:** Differs from a Category 1 application in that it is accompanied by two independent evaluation reports from comparable overseas regulators in whose jurisdiction the product is approved for the same indication.

  The legislated timeframes for the two stages of a Category 2 application are: 20 working days for notification of acceptance or rejection of an application and 175 working days to notify the applicant of the decision.
- **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.

  Examples of Category 3 applications include 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.

  The legislated timeframe for a Category 3 application is 45 working days for notification of acceptance or rejection of an application, completion of evaluation and notification of the decision.

1.1 Approval times

Once an application has been accepted by the TGA, the approval time is defined as the number of TGA working days until a decision is made. As detailed above, this timeframe is underpinned by legislation and excludes public holidays, weekends, the time allocated to the applicant to provide responses to requests for information and 'mutual clock stop' periods agreed with the applicant.

In accordance with the Therapeutic Goods Regulations 1990, a 'submission' may include a number of applications submitted at the one time. The data presented below relates to submissions as this best reflects the evaluation and decision-making processes.

Table 1 Prescription medicine approval times for January to June 2015

		Approval time			
Application type	**Legislated timeframe**	**Mean**	**Median**	**Minimum**	**Maximum**
A: New chemical entity					
Category 1	255	200	206	88	251
B: New fixed-dose combination					
Category 1	255	183	189	133	239
C: Extension of indication					
Category 1	255	192	206	40	240
D: New generic medicine					
Category 1	255	177	169	127	253
E: Additional trade name					
Category 1	255[a]	190	196	111	285
F: Major variation[b]					
Category 1	255	188	189	126	244
G: Minor variation[c]					
Category 1	255	0	0	0	0
Category 3	45	17	17	6	37
H: Minor variation[d]					
Category 1	255	131	101	56	237
Category 3	45	22	18	1	106
J: Changes to product information requiring the evaluation of data					
Category 1	255	152	162	18	245

[a] In July 2015, a new process with a new legislative timeframe was introduced for additional trade name submissions. During the reporting period relevant to this report, these applications were under the Category 1 framework and a legislated timeframe of 255 working days applied.

[b] During this reporting period, the TGA also approved one Category 2 application (F: Major variation) in 151 working days.

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

[d] The minor variations (type H) 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.

1.2 Submission outcomes

Table 2 Number of completed prescription medicine submissions by type and outcome for January to June 2015

Submission Type	Approved	Withdrawn	Rejected	Total
A: New chemical entity	16	1	1	18
B: New fixed-dose combination	7	0	0	7
C: Extension of indication	21	0	0	21
D: New generic medicine	56	6	0	62
E: Additional trade name	15	1	0	16
F: Major variation	21	2	0	23
G: Minor variation	70	0	0	70
H: Minor variation (Category 1)	3	0	0	3
H: Minor variation (Category 3)	652	3	1	656
J: Changes to Product Information	39	4	0	43
Total	900	17	2	919

1.3 Other applications

In addition to the application types discussed above, the TGA also processes numerous other application types. These applications are assessed in accordance with a risk-based approach, for example, some requests are categorised as 'self-assessable' and do not usually involve the evaluation of scientific data. Some applications are received because the sponsors are obliged to inform the TGA of new information related to the safety of their products. Other applications involve editorial corrections to the register entry or the associated product information document. The number of such applications is presented below.

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, the TGA may grant an 'exemption' from a particular standard for a product. The number of such applications approved and rejected is also included in the following table.

Table 3 Number of other Prescription Medicine applications

	2014		2015
	Jan–Jun	Jul–Dec	Jan-Jun
Safety related request	358	360	390
Self-assessable request	582	608	621
Minor editorial change to product information	264	272	281
Correction of error	98	94	69
Total	1302	1334	1361
Exemptions to comply with a standard			
Approved	N/A[a]	N/A[a]	34
Rejected	N/A[a]	N/A[a]	0
Total	N/A[a]	N/A[a]	34

[a] N/A – This data is not available as it was not being collected for these periods.

1.4 Orphan drug designations

'Orphan drugs' are often developed to treat small and very specific patient populations who suffer from rare diseases and conditions. The application and evaluation fees for orphan drugs can be waived to help reduce their development costs and facilitate their access to the Australian marketplace. A medicine needs to be designated by the TGA as an orphan drug before an application can be accepted to register it on the Australian Register of Therapeutic Goods (ARTG). The designation process involves a review of whether the drug meets the established criteria which are underpinned by legislation. The quality, efficacy and safety of orphan drugs are assessed at the same standard as for other registered prescription medicines.

Table 4 Number of orphan drug designations

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Number of designations	11	11	9

2 Over-the-Counter medicines

Over-the-Counter (OTC) medicines 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.

Table 5 Categorisation of OTC medicines applications

Application category	Definition
N1	An application submitted as a 'Clone'.
N2	An application which complies with an over-the-counter 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: is included in Appendix X (but which is not a level N1 application) and/or includes an umbrella branded product name where the umbrella segment is categorised as requiring a higher level of assessment and/or requires supporting safety and/or efficacy (clinical/toxicological) data or a justification for not providing such data.
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.
C1	Quality and non-quality changes.
C2	Quality changes or non-quality changes – no safety and efficacy data required.
C3	Umbrella branding – higher level of assessment or non-quality changes – safety and efficacy data may be required.
C4	Non-quality changes – data are required.

2.1 Approval times

Approval time is defined as the number of working days from the acceptance of the application until formal notification of decision. Approval time excludes time where the TGA was unable to progress the application until the sponsor provided additional information unless otherwise specified.

We aim to have 80% of applications completed within target timeframes. Target timeframes for processing of applications are a result of new OTC pre-market business processes and are subject to ongoing review.

Table 6 Mean approval time for OTC medicine applications

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
New medicine applications			
N1	21	30	23
N2	49	29	31
N3	97	51	66
N4	105	125	64
N5	N/A[a]	123	75
Change applications			
C1	16	8	12
C2	40	16	19
C3	33	84	47
C4	69	0	44

[a] The one N5 application processed to a decision in January to June 2014 was submitted prior to implementation of the new business process.

Table 7 OTC medicine approval time against target time by application category for January to June 2015

Application type	Number completed	Range	Mean	Median	Target time	% within target
New medicines						
N1	56	6-44	23	21	45	100
N2	1	N/A	31	31	75	100
N3	8	19-121	66	52	150	100
N4	10	29-106	64	59	170	100
N5	3	70-80	75	74	210	100

Application type	Number completed	Range	Mean	Median	Target time	% within target
Change applications						
C1	265	2-41	12	11	20	91
C2	126	0-64	19	11	64	100
C3	2	15-79	47	47	120	100
C4	5	44	44	44	170	100
Total	476					

Table 8 Percentage of OTC medicine applications processed within target time

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
New medicine applications (%)			
N1	98	94	100
N2	100	100	100
N3	100	100	100
N4	100	100	100
N5	N/A[a]	100	100
Change applications (%)			
C1	84	96	91
C2	98	99	100
C3	100	67	100
C4	100	N/A[b]	100

[a] The one N5 application processed to a decision in January to June 2014 was submitted prior to implementation of the new business process.

[b] There were no C4 applications finalised in this period.

2.2 Applications

2.2.1 New OTC medicine applications

Table 9 Applications received for new OTC medicines and changes to existing medicines

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
New medicine applications			
N1	138	88	56
N2	0	8	1
N3	18	21	28
N4	13	45	13
N5	5	8	6
Total	174	170	104
Change applications			
C1	183	255	290
C2	129	125	136
C3	8	2	2
C4	0	11	6
Total	320	393	434

2.2.2 Completed applications

Table 10 New OTC medicine applications completed and outcomes

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
N1			
Approved	131	106	56
Rejected	0	0	0
Withdrawn by sponsor	5	9	0
Returned/failed screening	0	1	0
Total	136	116	56
N2			
Approved	2	8	1
Rejected	0	0	0
Withdrawn by sponsor	0	0	0
Returned/failed screening	0	0	0
Total	2	8	1
N3			
Approved	38	19	8
Rejected	0	0	0
Withdrawn by sponsor	1	0	1
Returned/failed screening	2	2	7
Total	41	21	16
N4			
Approved	17	46	10
Rejected	1	0	0
Withdrawn by sponsor	0	5	1
Returned/failed screening	6	7	4
Total	24	58	15
N5			
Approved	1	12	3
Rejected	0	0	0
Withdrawn by sponsor	2	0	0
Returned/failed screening	2	5	4
Total	5	17	7

Table 11 OTC change applications completed and outcomes

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
C1			
Approved	184	257	265
Rejected	0	0	0
Withdrawn by sponsor	7	4	3
Returned/failed screening	0	0	0
Total	191	261	268
C2			
Approved	169	129	126
Rejected	0	0	0
Withdrawn by sponsor	1	4	6
Returned/failed screening	0	1	4
Total	170	134	136
C3			
Approved	6	3	2
Rejected	0	0	0
Withdrawn by sponsor	0	0	0
Returned/failed screening	0	0	0
Total	6	3	2
C4			
Approved	3	0	5
Rejected	0	0	0
Withdrawn by sponsor	0	0	0
Returned/failed screening	0	0	0
Total	3	0	5

3 Complementary medicines

3.1 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 the TGA for quality, safety and efficacy prior to being accepted on the Australian Register of Therapeutic Goods (ARTG).

Table 12 Registered complementary medicine applications by outcome

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
New medicines			
Approved	0	3	1
Rejected	0	1	0
Withdrawn	0	0	0
Returned/failed screening	0	0	0
Total new applications completed	0	4	1
Variations			
Approved	5	15	13
Rejected	0	1	0
Withdrawn	0	0	1
Returned/failed screening	0	0	0
Total variations completed	5	16	14
Application for consent to import, supply or export goods under section 14/14A of the Act[a]			
Approved	N/A[b]	N/A[b]	0
Rejected	N/A[b]	N/A[b]	0
Total applications [a] completed	N/A[b]	N/A[b]	0

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

[b] N/A – This data is not available as it was not being collected for these periods.

3.2 New ingredients permitted for use in listed medicines

Table 13 New listed medicine ingredient applications by outcome

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Approved	2	4	1
Rejected	4	0	1
Withdrawn	0	0	0
Returned/failed screening	0	0	0
Total completed	6	4	2

3.3 Listed medicines

Table 14 New listed medicines

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
New listed medicines	970	1 022	857

Table 15 Listed medicine variations under section 9D of the *Therapeutic Goods Act 1989*

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Approved	N/A[a]	N/A[a]	56
Rejected	N/A[a]	N/A[a]	3
Total	N/A[a]	N/A[a]	59

[a] N/A – This data is not available as it was not being collected for these periods.

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 in the ARTG is incomplete or incorrect.

Table 16 Listed medicine applications under section 14/14A of the *Therapeutic Goods Act 1989*

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Exemption Granted	N/A[a]	N/A[a]	2
Rejected	N/A[a]	N/A[a]	1
Total	N/A[a]	N/A[a]	3

[a] N/A – This data is not available as it was not being collected for these periods.

Sponsors can apply for certain exemptions under Section 14 of the *Therapeutic Goods Act 1989*. Applications seeking consent to import, export or supply a complementary medicine that does not comply with the applicable standards.

3.4 Listed medicine reviews

3.4.1 Investigations

Investigations include 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 17 Listed medicines investigations undertaken and outcomes

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Initiated investigations	49	38	48
Completed investigations			
Medicines prioritised for targeted review	N/A[a]	N/A[a]	24
Referred to another TGA area or government organisation	N/A[a]	N/A[a]	5
No further action taken	N/A[a]	N/A[a]	24
Total completed investigations	32	46	53

[a] N/A – This data is not available as it was not being collected for these periods.

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; advice was provided to the complainant.

3.4.2 Compliance reviews

Listed medicines are not evaluated by the TGA before they are included on the ARTG. However, a proportion is reviewed 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, 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 cancelled the medicine or information was not available to conduct the review and the review was closed and the compliance status was unable to be determined.

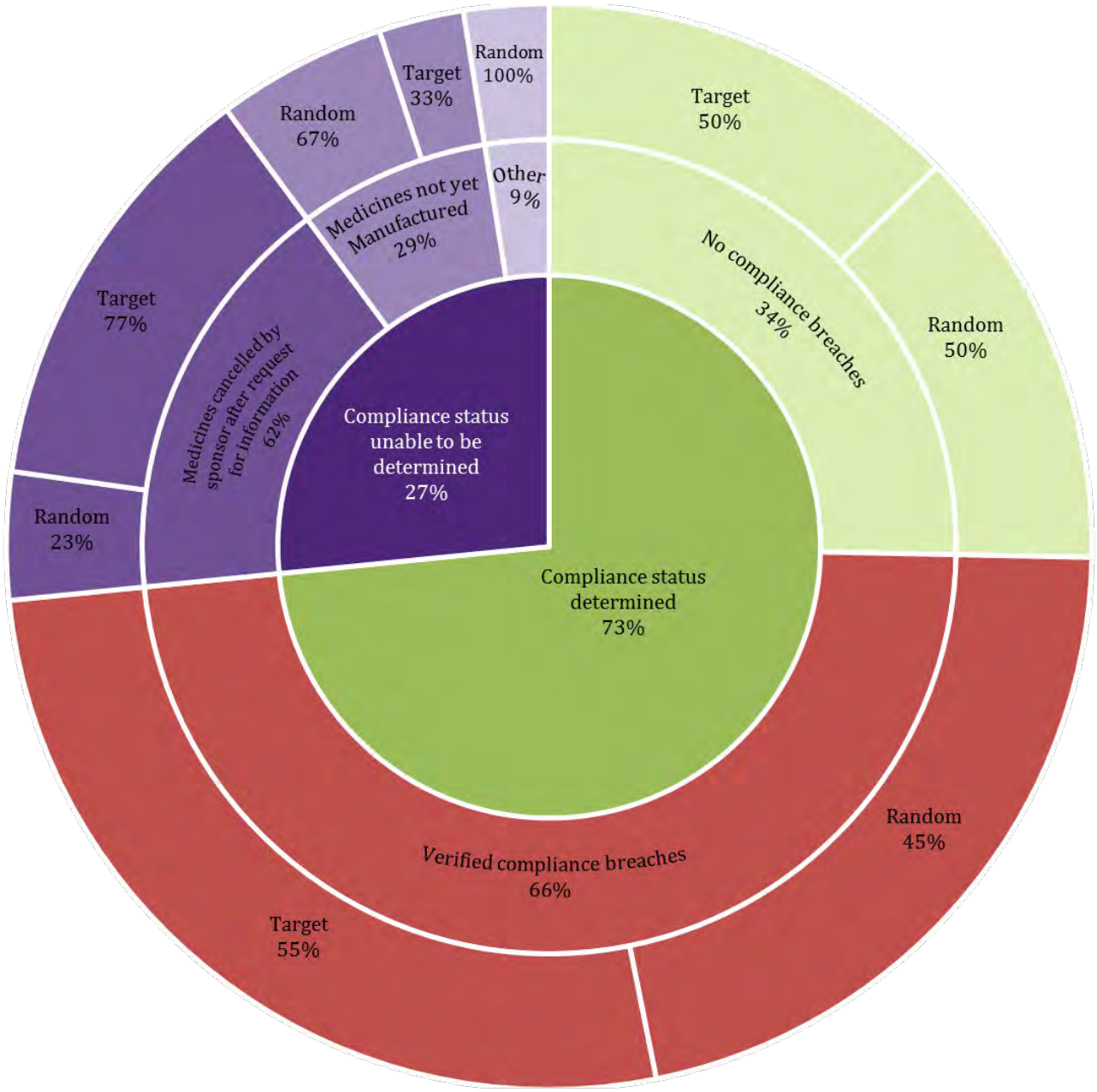
Table 18 Listed medicine reviews

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Initiated reviews			
Targeted reviews	47	21	20
Random reviews	22	13	76
Total	69	34	96
Reviews on hand	178	86	102
Completed reviews			
Targeted reviews	68	113	43
Random reviews	21	20	36
Total	89	133	79

Table 19 Outcomes of completed listed medicine reviews

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Compliance status determined			
Medicines with no compliance breaches	18	23	20
Medicines with verified compliance breaches	43	80	38
Sub-total	61	103	58
Compliance status unable to be determined			
Medicines cancelled by sponsors after request for information	18	18	13
Medicines not yet manufactured	10	12	6
Other	0	0	2
Sub-total	28	30	21
Product not a therapeutic good	0	0	0
Total completed	89	133	79

Figure 1 Outcomes of compliance reviews by reason for initiation



We are currently focussing on performing a higher number of random reviews than in previous periods to better inform our targeted compliance program. In this period, we were able to determine the compliance status of approximately three quarters of reviews we performed, and of these, around 34% were compliant. This is a higher rate of compliance compared to the previous period.

Table 20 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.

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Information provided in ARTG entry	4	3	6
Manufacturing, quality and/or formulation	8	6	9
Labelling and/or advertising	49	34	26
Evidence	14	25	17
Safety	0	0	0
Other	6	40	4

Figure 2 Types of compliance issues identified by reason for initiation

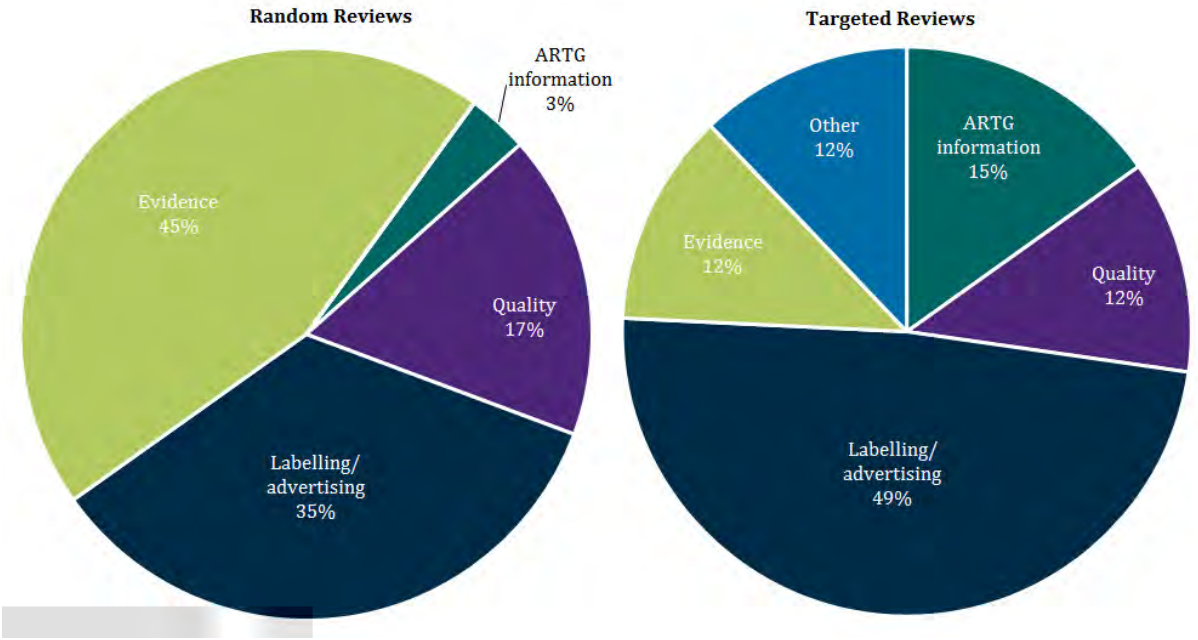


Figure 2 shows the types of compliance issues that are identified through reviews which are either randomly selected or targeted for a particular issue.

'Other' compliance issues may include the sponsor failing to comply with a condition that the medicine is subject to or not responding to a formal request for information.

For both random and targeted reviews, the most common compliance issues have consistently been labelling/advertising and evidence issues. It is apparent that compliance issues relating to evidence requirements dominate the types of issues identified during random reviews, while labelling/advertising issues are the most common issues identified during targeted reviews. A possible explanation for the higher proportion of labelling/advertising issues for targeted reviews may be that targeted reviews are often informed by complaints or referrals of potential non-compliance issues. As labelling and advertising requirements are easily accessible public information about listed medicines, these issues are often raised with the TGA more frequently and may explain the higher rate.

Table 21 Actions taken following listed medicine reviews

Actions following a Request for Information	
Medicines found to be compliant and review concluded	20
Medicines cancelled by the TGA without a proposal to cancel notice	1
Proposal to cancel notice sent by the TGA	37
Total	58
Actions following Proposal to Cancel notice	
Medicines cancelled by the TGA	6
Medicines cancelled by sponsors after being notified of compliance breaches	10
Reviews concluded after compliance breaches were addressed	21
Sub-total	37

The figures provided under 'Actions following Proposal to Cancel notice' are a sub-set of the figure provided under 'Actions following a Request for Information'.

Figure 3 Actions taken following listed medicine reviews categorised by compliance status

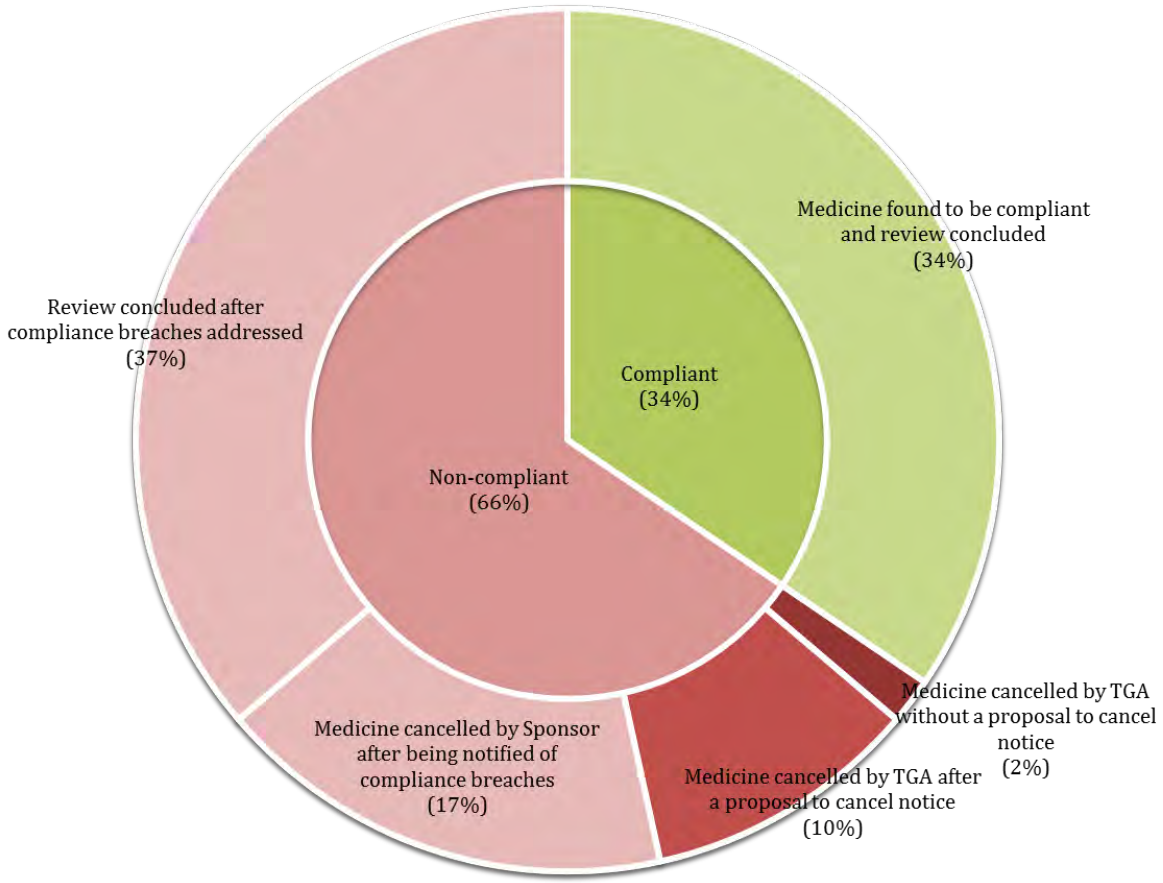


Figure 3 shows that a significant proportion of listed medicines reviews are concluded after the Sponsor has adequately addressed the compliance breaches identified by us. Under the *Therapeutic Goods Act 1989* sponsors are given an opportunity to respond to issues raised during a compliance review. This high proportion also shows that industry is willing to work with the TGA to ensure the supply of compliant medicines on the ARTG.

4 Biologicals

The *Australian regulatory guidelines for biologicals* defines the different Biological classes.

4.1 Inclusion of biologicals

Table 22 Applications for biologicals received and on hand

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Applications received			
Technical Master File (TMF) new	0	0	0
TMF annual updates	1	5	3
TMF variations	8	5	2
TMF notifications	4	5	3
Plasma Master File annual updates	12	6	10
Biological Class 2 – new applications	1	1	0
Biological Class 3 – new applications	0	0	0
Biological Class 2 – variations	0	2	3
Biological Class 3 – variations	4	1	1
Total received	30	25	22
Applications on hand			
Technical Master File (TMF) new	2	2	1
TMF annual updates	4	4	2
TMF variations	7	0	0
TMF notifications	3	2	0
Plasma Master File annual updates	6	7	8
Biological Class 2 – new applications	20	11	3
Biological Class 3 – new applications	2	2	2
Biological Class 2 – variations	0	1	0
Biological Class 3 – variations	1	1	4
Total on hand	45	30	20

Table 23 Completed applications for Biologicals

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Technical Master File (TMF) new	0	0	1
TMF annual updates	0	2	2
TMF variations	1	6	0
TMF notifications	1	5	0
Plasma Master File annual updates	6	9	8
Biological Class 2 – new applications	0	9	3
Biological Class 3 – new applications	0	4	2
Biological Class 2 – variations	0	1	0
Biological Class 3 – variations	3	0	4
Total completed	11	36	20

5 Medicine and vaccine adverse event reports

5.1 Adverse medicine and vaccine reaction notifications

Table 24 Source of notifications of medicine and vaccine adverse reaction

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Reports with clear causality, by reporter			
Hospitals	978	1 205	1 197
Companies	4 183	4 202	4 744
General practitioners	397	340	405
Specialists	93	122	106
Pharmacists	630	594	638
Members of the public (consumers)	298	231	319
Nurses, dentists, complementary healthcare practitioners	117	113	111
State/Territory Health departments	1 636	1 048	1 512
Reports withdrawn, or rejected, or without clear causality			
	952	797	973
Total received	9 284	8 652	10 005
Mean number of reports received weekly	357	332	385
Vaccine reports included in above table	2 008	1 276	1 983

6 Medical devices

The regulatory framework for medical devices spans the life cycle for these products, including:

- **Conformity assessment:** The systematic examination by the manufacturer to determine that a medical device is safe and performs as intended and, therefore, conforms to the Essential Requirements. Certification of the manufacturer's conformity assessment procedure may (and in some cases must) be undertaken by TGA, or the TGA 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 in the ARTG (unless a valid exemption applies).[1] A sponsor can apply to include a medical device in 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 in the ARTG the device must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.

6.1 Conformity assessment

6.1.1 Applications

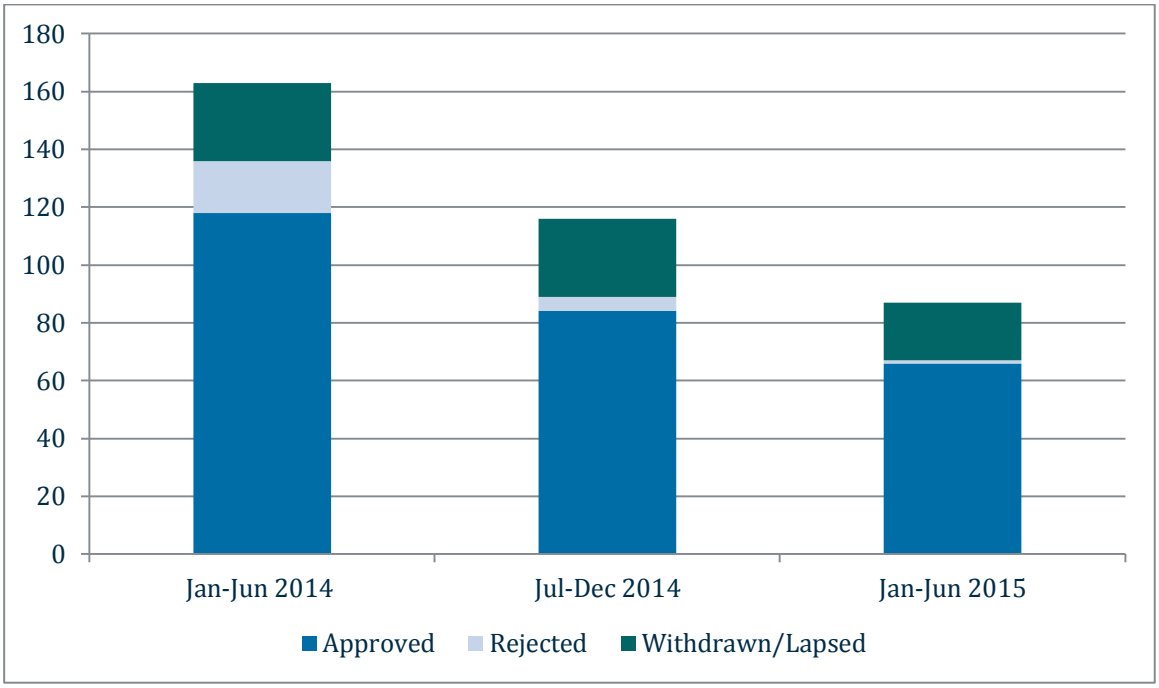
Table 25 Number of conformity assessment applications (medical devices including IVDs)

	2014		2015
	Jan–Jun	Jul–Dec	Jan-Jun
Applications received	98	112	81
Applications on hand	162	115	123
Applications completed	131	125	83

[1] Exemptions include custom made medical devices, importation of samples, etc.

6.1.2 Outcomes

Figure 4 Outcomes of conformity assessment applications



6.1.3 Processing times

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

Processing time is defined as the number of working days from the acceptance of the application until formal notification of decision. Under the Therapeutic Goods Regulations 1990, working days exclude public holidays and weekends. Processing time excludes time where the TGA was unable to progress the application until the sponsor provided additional information unless otherwise specified.

Table 26 Percentage of applications completed within target processing time

	2014		2015
	Jan–Jun	Jul–Dec	Jan-Jun
New devices	100%	100%	100%
Mean TGA processing times	119	137	122
Median TGA processing times	108	195	151
Changes or recertification	98%	100%	100%
Mean TGA processing times	86	93	77
Median TGA processing times	54	79	48

6.2 Inclusion of medical devices (including IVDs)

6.2.1 Applications

Table 27 Applications for inclusion – medical devices (including IVDs)

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Class 1 medical devices[a]			
Applications received	1405	1302	1201
Applications completed	1397	1303	1194
Class 1 measuring medical devices			
Applications received	24	33	41
Applications completed	27	30	44
Applications on hand[b]	7	3	4
Class 1 sterile medical devices			
Applications received	108	131	118
Applications completed	115	135	130
Applications on hand[b]	42	7	7
Class IIa medical devices			
Applications received	676	679	605
Applications completed	675	742	640
Applications on hand[b]	226	58	85
Class IIb medical devices			
Applications received	350	357	411
Applications completed	339	375	385
Applications on hand[b]	130	52	61
Class III medical devices			
Applications received	219	243	182
Applications completed	262	184	188
Applications on hand[b]	355	218	260
Class III Joint Reclassification medical devices[c]			
Applications received	150	114	523
Applications completed	329	231	133
Applications on hand[b]	891	252	538

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Active Implantable Medical Devices (AIMD)			
Applications received	25	37	14
Applications completed	49	42	4
Applications on hand[b]	50	23	51
Class 1 IVDs			
Applications received	86	53	103
Applications completed	79	72	86
Applications on hand[b]	8	3	7
Class 2 IVDs			
Applications received	145	77	169
Applications completed	127	104	123
Applications on hand[b]	28	5	30
Class 3 IVDs			
Applications received	108	55	168
Applications completed	90	74	109
Applications on hand[b]	34	15	22
Class 4 IVDs			
Applications received	24	14	43
Applications completed	23	15	40
Applications on hand[b]	1	0	0

[a] As Class I medical device applications are automatically included, 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.

[b] Applications on hand – figures shown are correct as of the date when the data was extracted

[c] The transition period for joint reclassification finished on 30 June 2015. A large number of applications were received at the end of this transition period, late in the January to June 2015 reporting period. As the transition period has now finished Class III joint reclassification applications will be rolled into the general Class III applications in future reports.

6.2.2 Outcomes

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

Table 28 Outcomes of medical device applications by classification for January to June 2015

	Number of applications		
Device Classification	Approved/Accepted	Rejected/Lapsed	Withdrawn
Class 1	1194	N/A	N/A
Class 1 Measurement	36	2	6
Class 1 Sterile	124	2	4
Class IIa	595	6	39
Class IIb	362	5	18
Class III	143	36	9
Class III Reclassification	119	1	13
AIMD	3	1	0
Class 1 IVD	85	0	1
Class 2 IVD	115	0	8
Class 3 IVD	92	0	17
Class 4 IVD	38	0	2

6.2.3 Processing times

The agreed target time 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'). This does not include the period the TGA is waiting for information or payment of fees (reflected in 'sponsor days').

Table 29 Processing times for medical devices application audits (including IVDs) for January to June 2015

	Number of applications	Mean Audit Processing Time	
		Sponsor days	TGA days[b]
Medical devices			
Applications completed without audit	1136[a]		
Non-compulsory audit[c]	220	28	47
Level 1 compulsory audit	11	17	5
Level 2 compulsory audit	155	42	82
IVDs			
Applications completed without audit	204[a]		
IVD non-compulsory audit	4	36	11
IVD compulsory audit	71	22	14

[a] These figures do not include applications for Class I and Class 1 IVD auto-included devices. These applications are complete within 24 hours.

[b] TGA time starts when the application is selected for audit, and it does not include public holidays and weekends, and the time when the TGA waits for information or payment from the sponsor.

[c] Non-compulsory audit – estimate for the audit processing time does not include applications for reclassification of join replacement medical devices received during transitional period (Class III Joint Reclassification medical devices), and applications supported by EC certificates issued by certain notified bodies (for details see <https://www.tga.gov.au/increased-application-audit-requirements-some-medical-devices-applications>).

6.3 Post-market monitoring

6.3.1 Automatically included entries

As Class I medical devices are automatically included without review by the TGA, post-market regulatory reviews are undertaken to ensure Class I are correctly included. This includes restricted word reviews, where applications for Class I devices are identified by the use of specific words indicative of risk or issues relating to the inclusion of the device, and targeted reviews that are initiated on a case by case basis (target reviews are conducted in relation to devices of any Class).

Table 30 Restricted word and targeted Class I medical devices reviews

	2014		2015
	Jan–Jun	Jul–Dec	Jan-Jun
Restricted word reviews			
Reviews completed	17	7	0
Reviews commenced	17	4	0
Reviews on hand	13	0	0
Targeted reviews			
Reviews completed	114	94	63
Reviews commenced	136	33	46
Reviews on hand	413	67	50

6.3.2 Post-market reviews

TGA also undertakes a range of post market reviews for devices above Class I.

Table 31 Medical device targeted reviews

	2014		2015
	Jan–Jun	Jul–Dec	Jan-Jun
Post market reviews			
Reviews commenced – number of ARTG entries	106	40	58
Reviews completed – number of ARTG entries	75	75	44
Reviews on hand – number of ARTG entries	121	87	96

6.3.3 Medical device incident reports

Processing time is defined as the number of working days from the receipt of the notification until the incident has been investigated and resolved. Under the Therapeutic Goods Regulations 1990, working days exclude public holidays and weekends.

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

Table 32 Number of medical device incident reports and processing times

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Reports received	1498	1662	1575
Reports completed	1578	2641	1499
Reports still in progress	498	169	155
Processing time			
Mean TGA processing time	59	19	14
Percentage processed within target timeframe	82%	86%	85%

Table 33 Medical device incident report outcomes [a]

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Reviewed and used for trend analysis purposes	862	1801	1248
Reviewed, no further action required	583	689	392
Product recall	42	23	39
Recall for product correction	18	5	13
Hazard alert	36	40	20
Product notification	0	1	0
Safety alert	46	11	8
Product enhancement/improvement notice	1	1	1
Instructions for use amended	26	15	11
Referral for post-market review	2	53	22
Referral to TGA Office of Manufacturing Quality	9	1	0
Refer to another TGA Office	35	28	27
Company warned	3	0	2
Product suspended from ARTG	0	0	0
Product cancelled from ARTG	1	1	5
Manufacturing process improvements	42	11	19
Quality system process improvements	5	8	3
Maintenance carried out by the hospital	1	0	0
Change to design	6	11	3
Not device related	9	6	1
Other	97	119	44

[a] Outcomes are not mutually exclusive

7 Exports

Processing time is defined as the number of working days from the acceptance of the application including payment until formal notification of decision. Under the Therapeutic Goods Regulations 1990, working days exclude public holidays and weekends. Processing time excludes time where the TGA was unable to progress the application until the sponsor provided additional information unless otherwise specified.

7.1 Export only medicines

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

Table 34 Mean approval times for export only medicines

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
New applications			
Mean TGA processing time	24	20	21
Percentage processed within target processing time	98%	100%	100%
Variations			
Mean TGA processing time	22	12	13
Percentage processed within target processing time	98%	100%	98%

Table 35 Applications for new and variations to export only medicines

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Applications received	113	112	102
Applications awaiting response from sponsor	0	6	17
Applications completed			
Approved	N/A[a]	N/A[a]	100
Withdrawn	N/A[a]	N/A[a]	2
Total completed	N/A[a]	N/A[a]	102

[a] N/A – This data is not available as it was not being collected for these periods.

7.2 Export certifications for medicines

The target processing time for applications for an export certificate for a medicine is 15 working days. We aim to have 100% of applications processed within the target timeframe.

Table 36 Export certification applications and mean processing times

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Applications received	1078	1146	1044
Applications completed			
Approved	1093	1155	1024
Withdrawn	0	0	4
Total completed	1093	1155	1028
Processing times			
Mean TGA processing time	12	12	13
Percentage processed within target time	98%	99%	97%

7.3 Export certification assessment for medical devices

The target processing time for applications for an export certificate for a medical device is 5 working days. We aim to have at least 90% of applications processed within the target timeframe.

Table 37 Medical device applications and mean processing times for export certification assessments

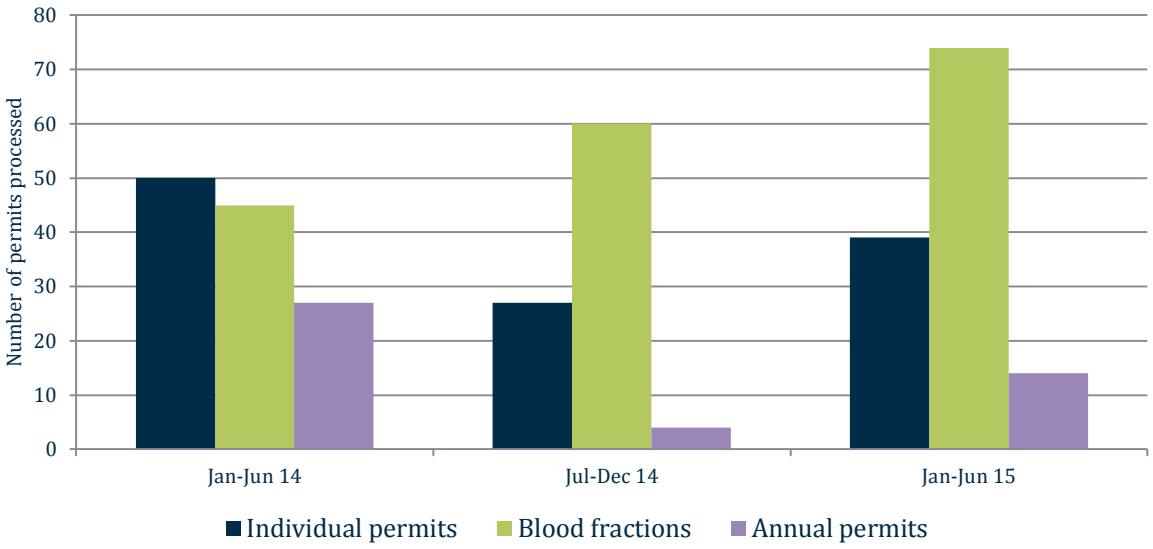
	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Applications received	222	239	341
Applications completed			
Export certificates issued	198	255	327
Applications withdrawn	0	8	5
Total completed	198	263	332
Processing time			
Mean TGA processing time	3	3	3
Percentage processed within target time	98%	95%	95%

7.4 Blood permits for export

The TGA issues 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 who 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 for taking 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 5 Number of blood permits processed



8 Access to unapproved therapeutic goods

8.1 Special access scheme

The Special Access Scheme (SAS) provides for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. Patients are grouped into two categories under the scheme:

- Category A: persons 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. In this case prescribers are required to *notify* the TGA of the use.
- Category B: all other patients. In this case prescribers are required to *apply* to the TGA for the use.

Table 38 SAS medicines notifications and applications

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Category A notifications			
Total Category A notifications	17 648	18 698	19 162
Category B applications			
Approved	9 675	10 338	10 869
Cancelled	181	172	328
Rejected	22	47	14
Pending at end of reporting period	32	74	43
Total Category B applications	9 910	10 631	11 254

Table 39 SAS devices notifications and applications

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Category A notifications			
Total Category A notifications	1139	1968	1488
Category B applications			
Approved	1159	1121	950
Cancelled	11	75	100
Rejected	16	17	10
Pending at end of reporting period	65	5	17
Total Category B applications	1251	1218	1077

Table 40 SAS biologicals notifications and applications

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Category A notifications			
Total Category A notifications	24	38	77
Category B applications			
Approved	1135	1225	1217
Cancelled	0	0	0
Rejected	4	1	0
Pending at end of reporting period	23	0	22
Total Category B applications	1162	1226	1239

8.2 Clinical trials

Clinical trial notifications provide access to unapproved therapeutic goods where patients are participating in a clinical trial. Notifications are based on trial sites; however an application can be made to extend the trial to other locations. Unapproved therapeutic goods can include biologicals, devices or medicines or a combination of any of the three types of goods.

Table 41 New trial notifications that include unapproved therapeutic goods received by State or Territory (single and multi-site trials)

			NSW	Vic	Qld	SA	WA	Tas	ACT	NT	Total
2014	Jan–Jun	Medicine	123	92	26	25	11	1	0	0	278
		Device	30	18	4	0	4	0	0	0	56
		Biological	1	1	1	0	0	0	0	0	3
		Medicine and device	72	19	8	7	4	0	0	0	110
		Device and biological	0	0	1	0	0	0	0	0	1
		Medicine and biological	0	1	0	0	0	0	0	0	1
	Jul–Dec	Medicine	97	95	47	20	14	3	2	0	278
		Device	35	18	4	3	10	0	0	0	70
		Biological	1	2	2	0	2	0	0	0	7
		Medicine and device	113	32	3	11	3	0	0	0	162
		Device and biological	0	0	1	0	0	0	0	0	1
		Medicine and biological	0	0	0	0	0	0	0	0	0
2015	Jan–Jun	Medicine	49	91	29	26	25	6	2	0	228
		Device	19	25	3	10	11	1	1	0	70
		Biological	0	0	1	0	0	0	0	0	1
		Medicine and device	42	62	33	21	20	3	4	0	185
		Device and biological	0	0	0	0	0	0	0	0	0
		Medicine and biological	0	0	0	0	0	0	0	0	0

Table 42 New trial notifications that include unapproved therapeutic goods by phase (total number of trial sites notified)

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Clinical trial type			
Phase 1	68	83	77
Phase 2	130	124	143
Phase 3	153	198	170
Phase 4	32	34	37
Bioavailability/equivalence	2	3	2
None specified	64	76	70
Total	449	518	499

Table 43 All notifications (includes new trials and new sites for existing trials) that include unapproved therapeutic goods, received by State or Territory (single and multi-site trial sites notified)

			NSW	Vic	Qld	SA	WA	Tas	ACT	NT	Total
2014	Jan–Jun	Medicine	601	400	86	52	22	5	1	0	1167
		Device	93	41	4	0	4	0	0	0	142
		Biological	6	1	0	0	0	0	0	0	7
		Medicine and device	376	81	49	31	5	3	0	0	545
		Device and biological	0	0	1	0	0	0	0	0	1
		Medicine and biological	0	0	0	0	0	0	0	0	0
	Jul–Dec	Medicine	297	285	209	102	76	14	14	5	1002
		Device	36	41	11	15	13	0	1	0	117
		Biological	1	3	4	0	2	2	0	0	12
		Medicine and device	191	252	140	102	62	11	9	1	768
		Device and biological	1	0	0	0	0	0	0	0	1
		Medicine and biological	0	0	0	0	0	0	0	0	0
2015	Jan–Jun	Medicine	234	296	173	91	101	20	9	1	925
		Device	32	46	9	14	16	1	1	0	119
		Biological	0	0	2	0	0	0	0	0	2
		Medicine and device	252	300	208	121	100	21	7	1	1010
		Device and biological	0	0	0	0	0	0	0	0	0
		Medicine and biological	0	0	0	0	0	0	0	0	0

Table 44 All notifications

This includes new trials and new sites for existing trials that include unapproved therapeutic goods received by phase (total number of trial sites notified).

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Clinical trial type			
Phase 1	94	131	131
Phase 2	421	436	583
Phase 3	978	1088	1184
Phase 4	210	116	154
Bioavailability/equivalence	5	4	2
None specified	154	125	136
Total	1862	1900	2190

8.3 Authorised prescribers

Table 45 Authorised prescriber approvals for medicines and medical devices

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Number of approvals for medicines	213	324	356
Number of approvals for medical devices	88	129	144

Licencing and manufacturing

8.4 Manufacturing licences

Table 46 Manufacturing licence applications and status of existing licences

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
New licences granted	12	8	11
Withdrawn application	23	21	35
Revoked licences – voluntary	13	6	22
Revoked licences – TGA	0	0	0
Ceased	0	0	0
Suspended – Voluntary	1	0	0
Suspended – TGA	0	0	0

As at 30 June 2015, there were 404 Australian companies holding manufacturing licences covering 448 sites.

Table 47 Manufacturing licence application outcomes

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Inspections conducted	78	102	96
Satisfactory compliance	89%	97%	89%
Marginal compliance	10%	3%	11%
Unacceptable	1%	0%	0%
Processing time			
Initial inspections conducted within 3 months of application	87%	88%	100%
Re-inspections conducted within 6 months of due date	64%	67%	64%

Applicants often submit applications for Good Manufacturing Practice (GMP) licences before completing all of their systems and processes. It is therefore common for initial applications to be conducted later than the target of 3 months.

8.5 Manufacturing certifications

Table 48 Manufacturing certification application by status

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
New applications received	69	38	56
Re-inspection applications	87	83	69
Applications completed			
Certified	77	67	48
Rejected	0	39	98
Total completed	77	106	146

As at 30 June 2015, there were 419 overseas manufacturers covering 446 manufacturing sites.

Table 49 Manufacturing certification outcomes

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Inspections conducted	53	47	86
Satisfactory compliance	83%	86%	94%
Marginal compliance	17%	11%	4%
Unacceptable	0%	3%	2%
Processing time			
Initial certifications inspections conducted within 6 months of application	68%	90%	84%
Certification re-inspections conducted within 6 months of due date	51%	81%	80%

Applicants often submit applications for GMP certification before completing all of their systems and processes. It is therefore common for initial applications to be conducted later than the target of 6 months.

8.6 Good Manufacturing Practice (GMP) clearances

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

Table 50 GMP clearance application status

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Applications received	1875	1998	2050
Renewal applications	420	684	1141
Applications completed			
Approved	3539	1897	2550
Rejected	73	224	91
Total completed	3612	2123	2641

9 Recalls

9.1 Medicine recalls

Table 51 Medicine recalls by reason for recall

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Adverse reactions	1	0	2
Foreign matter	0	3	3
Illegal supply	0	0	0
Impurity and degradation	3	3	4
Labelling and packaging	5	8	5
Micro-organisms	0	0	2
pH	0	0	2
Potency	1	1	1
Sterility	1	1	1
Other [a]	9	6	3
Total	20	22	23

[a] 'Other' includes dissolution, physical defects, observed differences, variable content, diagnostic inaccuracy and wrong product.

9.2 Medical device recalls

Table 52 Medical device (including IVDs) recalls by reason for recall

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Adverse incidents	0	1	3
Diagnostic inaccuracy	29	38	33
Electrical defect	17	25	16
Illegal supply	0	0	1
Labelling and packaging	61	43	56
Mechanical and physical defects	100	96	97
Software defects	69	59	55
Sterility	2	5	4
Other [a]	9	24	21
Total	287	291	286

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

9.3 Biologicals recalls

Table 53 Biologicals recalls

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Recalls to hospital level	2	0	0

10 Laboratory testing

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

Information on the Laboratories Branch activities and Laboratory Testing Plan can be found on the TGA website.

Table 54 Samples and products tested by type of therapeutic good and percentage which failed

		2014		2015
		Jan–Jun	Jul–Dec	Jan–Jun
Prescription medicines	Total	540	377	483
	% fail	1%	1%	0.2%
OTC medicines	Total	15	20	24
	% fail	0%	40%	21%
Complementary medicines	Total	200	77	79
	% fail	27%	30%	13%
Medical devices	Total	69	75	42
	% fail	30%	19%	7%
Contract [a]	Total	47	23	60
	% fail	0%	22%	3%
Unregistered [b]	Total	186	166	111
	% fail	82%	54%	84%
Total samples per half year [c]		1289	1013	980
Total samples per half year (excluding AHQ samples)		1057	738	799
Percentage fail per half year		22%	19.6%	14.3%
Total number of products tested per half year [d]		507	403	405

[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] Includes accreditation, harmonisation and quality control (AHQ) samples.
[d] The TGA may test a number of samples of each product per reporting period.

Table 55 Samples that failed laboratory testing by reason for failed between January and June 2015

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Complementary medicines	Total
Contamination	0	0	0	3	7	10
Formulation	0	2	1	86	1	90
Label and packaging deficiencies	0	0	0	0	1	1
Performance	2	0	0	4	1	7
Physical or mechanical properties	1	3	0	0	0	4
Total	3	5	1	93	10	112

Table 56 Batch release and export certification

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Batch release [a]	225	152	242
Export certification	36	5	9

[a] Vaccines, biotechnology and blood products: evaluation of batch release documentation.

Table 57 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	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

Compliance against these timeframes are outlined in table 58.

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

Table 58 Compliance with testing timeframes between January and June 2015

	Priority	Total	Percentage
Medical devices	Routine	64	56%
	Priority	6	100%
	Urgent	1	100%
OTC medicines	Routine	26	96%
	Priority	0	N/A
	Urgent	0	N/A
Prescription medicines	Routine	125	70%
	Priority	3	100%
	Urgent	31	94%
Complementary medicines	Routine	87	81%
	Priority	3	67%
	Urgent	2	100%
Unregistered products	Routine	2	0%
	Priority	78	94%
	Urgent	24	100%

Low numbers of samples within categories may affect compliance percentages. Urgent testing may impact on the timeframes for priority and routine testing.

11 Regulatory compliance

Using signals from numerous sources as intelligence, the TGA Regulatory Compliance Unit conducts compliance and enforcement activities against a risk based compliance framework. Using principles of responsive regulation, a range of tools are used including encouragement and guidance to comply, restrictions or warnings, suspensions or sanctions and cancellations. At the apex, activities including investigations into illegal import or manufacture of unapproved and counterfeit therapeutic goods can result in criminal or civil court action. All compliance activities have the intended purpose to protect public health.

Table 59 Regulatory compliance investigations by final action taken

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Investigation in progress	257	168	73
Completed investigations			
Warned	371	291	398
No offence detected	100	82	59
Goods released under Personal Import Scheme	33	29	45
Referred to another agency or department outside Health	8	5	4
Referred to another branch within the TGA	8	1	3
Import treated as abandoned goods by Customs	0	0	0
Recall of goods	2	0	0
Matters referred to the Commonwealth Director of Public Prosecutions	3	0	1
Total completed	525	408	510

Table 60 Types of products investigated

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Complementary medicines	421	260	226
Prescription medicines	318	383	477
Medical devices	100	81	75
Homoeopathic medicines	1	2	2
OTC medicines	9	32	54
Biological products	0	5	25
Other	18	14	17
Total	867	777	876

Table 61 Regulatory compliance investigations by special interest categories

	2014		2015
	Jan–Jun	Jul–Dec	Jan–Jun
Unapproved product	678	677	727
Counterfeit product	172	92	140
Parallel import/export	2	0	1
Manufacture without licence	1	0	0
Advertising offence	0	1	2
Traditional Chinese medicines	0	1	0
Other[1]	6	2	2
Total	859	773	872

[1] Products that fall outside the remit of the *Therapeutic Goods Act 1989*, for example Food products

Table 62 Investigations by complainant type and state/territory for January to June 2015

Origin	ACT	NSW	NT	QLD	SA	VIC	WA	Other [a]	Total
Complaints resolution	3	8	0	1	0	0	0	0	12
Customs	1	200	5	64	4	105	42	2	423
External agency	5	11	0	5	1	1	0	0	23
General public	0	12	1	10	1	10	1	68	103
Patient/ practitioner	0	0	0	0	0	0	0	1	1
Sponsor/client	0	0	0	0	0	1	0	3	4
TGA internal	25	0	0	0	0	0	0	0	25
Total	34	231	6	80	6	117	43	74	591

[a] Other includes investigations of reports from Tasmania and anonymous (unknown) origin.

Therapeutic Goods Administration

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