Australian Government
Department of Health
Therapeutic Goods Administration

Half-yearly performance report

July to December 2014

Version 1.0, March 2015

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <http://www.tga.gov.au>.

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What the TGA regulates

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

As part of the Department of Health, the TGA safeguards and enhances the health of the Australian community through effective and timely regulation of therapeutic goods.

The TGA is responsible for ensuring that therapeutic goods available for supply in or exported from Australia are safe and fit for their intended purpose. These include goods Australians rely on every day, such as vitamin tablets and sunscreens, through to goods used to treat serious conditions, such as prescription medicines, vaccines, blood products and surgical implants.

The TGA regulates the supply, manufacturing and advertising of these products:

- medicines prescribed by a doctor or dentist
- medicines available from behind the pharmacy counter
- medicines available in the general pharmacy
- medicines available from supermarkets
- complementary medicines, these include 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), such as blood tests; and
- vaccines, blood products, and other biologics.

How the TGA regulates

The Australian community expects therapeutic goods in the marketplace to be safe, of high quality and of a standard at least equal to that of comparable countries.

The TGA regulates therapeutic goods through:

- premarket assessment and market authorisation
- postmarket monitoring and enforcement of standards; and
- ensuring manufacturing facilities, whether in Australia or overseas, comply with internationally recognised standards.

Therapeutic goods are divided broadly into three classes: biologicals, medicines and medical devices. Unless exempt, biologicals and medical devices must be 'included' and medicines must be entered as either 'registered' or 'listed' medicines on the Australian Register of Therapeutic Goods (ARTG) before they may be supplied in or exported from Australia.

If a problem is discovered with a medicine, device or manufacturer, the TGA is able to take a variety of regulatory actions. Possible actions vary and may include continued monitoring through to withdrawing the product from the market or in some circumstances referral to the

Commonwealth Director of Public Prosecutions for possible prosecution in relation to criminal offences.

Regulating medicines

The regulation of medicines includes the following features:

- classifying the medicine based on different levels of risk to the person taking them
- implementing appropriate regulatory controls for the manufacturing processes of medicines
- medicines assessed as having a higher level of risk (prescription medicines, some non-prescription medicines) are evaluated for quality, safety and efficacy
- ingredients in medicines with a lower risk (medicines purchased over the counter, such as complementary medicines) are required to meet standards for quality and safety
- medicines determined to be available for lawful supply by the TGA can be identified by either an AUST R number or an AUST L number on the outer packaging. Please note, there are a small number of medicines that are exempt and do not require this information on the label
- once available for supply, medicines are subject to monitoring by the TGA. This monitoring includes a comprehensive adverse event reporting programme that allows safety problems to be identified and actions taken to minimise any further potential for harm to patients.

Regulating medical devices

The regulation of medical devices includes:

- classifying the medical device based on different levels of risk to the user
- assessing compliance with a set of internationally agreed essential principles for their quality, safety and performance
- implementing appropriate regulatory controls for the manufacturing processes of medical devices
- including the medical device in the ARTG
- once available for supply, medical devices are subject to monitoring by the TGA. This monitoring includes a comprehensive adverse event incident reporting programme that allows for early identification of potential safety issues.

Other therapeutic goods regulated by the TGA

The TGA also applies a risk management approach to the regulation of:

- in vitro diagnostic medical devices (IVDs)
- blood
- blood components
- plasma derivatives
- tissue and cellular products

- tissue and cell based derivatives
- sterilants and disinfectants.

The half-yearly performance report

The TGA provides information twice-yearly on our regulatory performance to our stakeholders through detailed statistical reports. This half-yearly performance report covers the period July to December 2014.

Our performance against our broad strategic intent is measured through twice-yearly reporting against eight agreed key performance indicators in *TGA key performance indicators*[1] reports.

Key observations: July to December 2014

Market authorisation

Prescription medicines

- The number of submissions to register new prescription medicines, or to make significant variations to an existing prescription medicine (Category 1), has remained relatively consistent with previous periods over 2013 and 2014.
- Category 3 submissions (variations to existing medicines that do not need to be supported by clinical, non-clinical or bioequivalence data) have remained relatively consistent with previous periods over 2013 and 2014.
- All other submissions have remained relatively constant overall.
- Mean processing times for Category 1 and 3 applications were well below the statutory timeframes of 255 days and 45 days respectively.

Over The Counter (OTC) medicines

- There was an increase in the total number of applications received compared with January-June 2014, although the number falls within the variability of previous periods. The number of N4 applications has tripled compared with January-June 2014.
- There continues to be a high volume of applications to make quality and non-quality related changes (C1 and C2), compared to new applications.
- Mean processing times for all types of applications were well below the agreed target timeframes. The percentage of applications completed within target timeframes was consistently higher than the 80% target.

Complementary medicines

- There was one new registered complementary medicine application received between July and December 2014, which is equivalent to the previous reporting period.

[1] <https://www.tga.gov.au/publication/tga-key-performance-indicators-january-june-2014>

- The number of newly listed complementary medicines entered on the Australian Register of Therapeutic Goods between July and December 2014 is similar to the number of new entries reported in the previous reporting period of January to June 2014.
- The total number of new listed medicines in 2014 showed a 28% increase from 2013.

Medical devices

- In 2012, joint implants were reclassified from Class IIb to Class III. After an initial large increase in May and June 2013 (coinciding with the end of the waiver of application fees), the number of Class III joint reclassification applications received has noticeably reduced during the last three reporting periods.
- The high number of joint reclassification applications has impacted on resource allocation for audit assessments of other applications. Therefore, timeframes for level 2 compulsory audit assessments and non-compulsory audit assessments are currently not meeting the target timeframes. However over the past 18 months, the number of outstanding application audits has gradually reduced for level 1 compulsory audit assessments and non-compulsory audit assessments.

Special access scheme for medicines

- The number of Category A notifications for use in patients who are terminally ill or seriously ill or have life-threatening conditions have steadily increased for all types of therapeutic goods; medicines, devices and biologicals. For medicines, the total number of Category A notifications in 2014 showed a 3.7% increase from 2013 (2013:35,049 notifications; 2014: 36,346 notifications). For devices, the total number of Category A notifications in 2014 showed a 40% increase from 2013 (2013: 2,210 notifications; 2014: 3,107 notifications in 2014). Of significant note, the total number of Category A notifications for biologicals showed a 342% increase in 2014 (2013: 14 notifications; 2014: 62 notifications).
- The number of Category B applications for use in patients other than those with terminally ill or seriously ill/life threatening conditions decreased slightly for medicines and devices, but increased significantly for biologicals. The total number of Category B applications specifically for biologicals in 2014 showed a 25% increase from 2013 (2013: 1,926 applications; 2014: 2,400 applications).

Postmarket activities

Licencing and manufacturing

- As at 31 December 2014, there were 414 Australian companies holding manufacturing licences covering 457 sites.
- Between July and December 2014, 97% (99 out of 102) of licence application inspections of Australian manufacturers were found to have satisfactory compliance and the remaining 3% (3 out of 102) were found to have basic compliance.
- As at 31 December 2014, 2681 overseas manufacturers of therapeutic goods were approved to supply the Australian market. Of these, 410 overseas manufacturers covering 422 sites were approved following a TGA inspection. The remainder were approved based on inspections conducted by equivalent international regulatory authorities.

- Between July and December 2014, 86% (41 out of 47) of certification inspections for assessment were found to have satisfactory compliance, a further 11% (5 out of 47) were found to have marginal compliance and 3% (1 out of 47) were found to be unacceptable.

Therapeutic goods recalls

- Between 1 July and 31 December 2014, there were a total of 366 recall actions coordinated by the TGA, comprising 22 medicines, 291 medical devices (including in vitro diagnostic medical devices; IVDs), and 53 process-related blood product recall actions.
- The average numbers of recall actions for a six month period over the last three years were: 26 (medicines), 284 (medical devices including IVDs), 1 (biological) and 46 (blood products).

Medicine and vaccine adverse event reports

- Reporting of medicine and vaccine adverse events peaked in 2013 with over 20,000 adverse event case reports received and remains above 17,000 reports being received annually. Hospital adverse event reports increased in the second half of 2014 by 28% compared to the previous year. The reason for the fluctuation is usually due to normal variation that can occur in a spontaneous reporting system. In this case it is also likely that changes in reporting requirements for sponsors regarding reporting of adverse events associated with patient support programs would have reduced the number of reports from sponsors. These reports are now considered solicited and are not required to be reported (this is also the case in the European Union).

Regulatory compliance

- Between July and December 2014, we dealt with 576 alleged offences. The types of investigations included illegal import, supply, manufacture, claim and export. None of these offences required resolutions through the court system and therefore there were no convictions, however, one enforceable undertaking was entered into during this period as an alternative to court action. Please see Enforceable undertaking: Nutrition Warehouse Pty Limited[2].

[2]<https://www.tga.gov.au/compliance-undertaking/enforceable-undertaking-nutrition-warehouse-pty-limited>

Key statistics: July to December 2014

Total products on the Australian Register of Therapeutic Goods (ARTG)

Category	Number
Biologicals	15
Prescription medicines	14,990
OTC medicines	3419
Listed medicines	12,301
Registered Complementary Medicines	141
Export only medicines	2708
IVDs (including export only IVDs)	1712
Medical Devices (including other therapeutic goods and export only medical devices)	46,821
Total	82,107

Medicines registrations processed by TGA

Type of medicine registration	Number
Prescription Medicines	
New medicine entries	815
Changes (major and minor)	9070
Cancellations	87
Over-the-counter Medicines	
New medicine entries	198
Changes (major and minor)	132
Cancellations	30
Complementary Medicines	
New medicine entries	3
Changes (major and minor)	15
Cancellations	37

Medicine listings processed by TGA

Type of listing processed	Number
Medicines for supply in Australia	
New medicine entries	1022
Changes (major and minor)	596
Cancellations	370
Medicines for export only	
New medicine entries	63
Changes (major and minor)	39
Cancellations	17

Medical devices inclusions processed by TGA

Medical device inclusions processed	Number
Included medical devices	
New entries	2863
Cancellations	688
Included medical devices for export	
New entries	366
Cancellations	12
Included IVD medical devices	
New entries	220
Cancellations	11
Included IVD medical devices for export	
New entries	0
Cancellations	0
Other therapeutic goods	
New entries	12
Cancellations	33
Other therapeutic goods for export	
New entries	0
Cancellations	0

Recall information

Recall level	Medicines	Devices	Biologicals
Recalls to consumer level	1	4	0
Recalls to retail level	10	17	0
Recalls to hospital level	8	270	0
Recalls to wholesale level	3	0	0
Total	22	291	0

Medicines adverse reaction reporting

Incoming adverse medicine reaction reports	Number
Hospitals	1205
Companies	4202
General Practitioners	340
Specialists	122
Pharmacists	594
Members of the Public (Consumer)	231
Nurses, dentists, complementary	113

Incoming adverse medicine reaction reports	Number
State/Territory Health Department	1048
General list (cause unclear) includes rejected and withdrawn	797
Total	8652

Medical device incident reports

Type of report received	Number
User reports	458
Sponsor reports	2593
Total	3051

1. Market authorisation

1.1 Prescription medicines

Table 1 Definitions and specified periods (statutory timeframes)

Application category	Definition	Specified period	Working days
Category 1 application	An application to register a prescription medicine via the normal process of evaluation. Examples of Category 1 applications are new substances, extensions of indication, and new routes of administration.	Notification of acceptance or rejection of an application Completion of evaluation	40 255
Category 2 application	An application to register a prescription medicine with the same formulation, dosage and indications as in two acceptable countries and for which two independent evaluation reports are available.	Notification of acceptance or rejection of an application Completion of evaluation	20 175
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, e.g. change in site of manufacture.	Period in which to make a decision or raise an objection From acceptance to delegate's decision	45 45

In the case of prescription medicines, an 'application' relates to a single change to a single product. A 'submission' includes a number of applications submitted at the one time, in accordance with the Therapeutic Goods Regulations 1990 (the Regulations). The TGA tracks each submission and each product application within each submission.

Category 2 submissions are rarely received. They will only be documented in this report if a submission has been processed.

1.1.1 Workflow of applications

Table 2 Workflow of Category 1 pre-submissions and submissions and Category 3 submissions

	2013		2014	
	Jan-Jun	Jul–Dec	Jan–Jun	Jul-Dec
Overall				
Pre-submissions/submissions received[1]	894	1029	936	929
Submissions finalised[2]	900	1022	960	919
On hand at end of reporting period	656	663	639	666
Category 1				
Pre-submissions received[1]	219	235	238	228
Submissions finalised[2]	191	230	206	174
On hand at end of reporting period	534	539	571	588
Category 3				
Submissions received	675	794	698	701
Submissions finalised[2]	709	792	754	745
On hand at end of reporting period	122	124	68	78

In the case of prescription medicines, an applicant must first lodge a 'pre-submission', which provides details of a proposed application, at least 2¼ months prior to lodgement of the full 'submission', allowing the TGA to identify milestone dates and plan resource requirements.

[1]Includes submissions still in the pre-submission stage

[2]Includes submissions withdrawn or rejected at acceptance for evaluation stage

Table 3 Category 1 pre-submissions received by fee category and the number of submitted applications for those pre-submissions

	2013				2014			
	Jan–Jun		Jul–Dec		Jan–Jun		Jul–Dec	
Fee category	Pre-subs	Apps	Pre-subs	Apps	Pre-subs	Apps	Pre-subs	Apps
New Chemical Entity	28	96	24	50	17	38	32	55
Extension of indications	22	70	16	43	20	30	22	33
Major variation	20	86	18	80	25	27	25	37
New generic product	78	613	75	670	71	331	87	371
Additional trade name	19	90	13	50	28	40	20	99
Minor variation	5	23	14	6	3	6	6	9
Changes to PI with evaluation	47	160	42	135	47	57	36	42
All Others	0	0	33	0	27	0	0	0
Total	219	1138	235	1034	238	529	228	646

PI=Product Information; Pre-subs=pre-submissions; Apps=applications.

Table 4 Number of submissions other than Category 1, 2 and 3

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Safety related request	392	437	358	360
Self-assessable request	735	685	582	608
Minor editorial change to PI	94	299	264	272
Correction of error	55	87	98	94
Request for Orphan Drug Designation	8	10	11	11
Not yet determined	0	0	0	0
Total	1284	1518	1313	1345

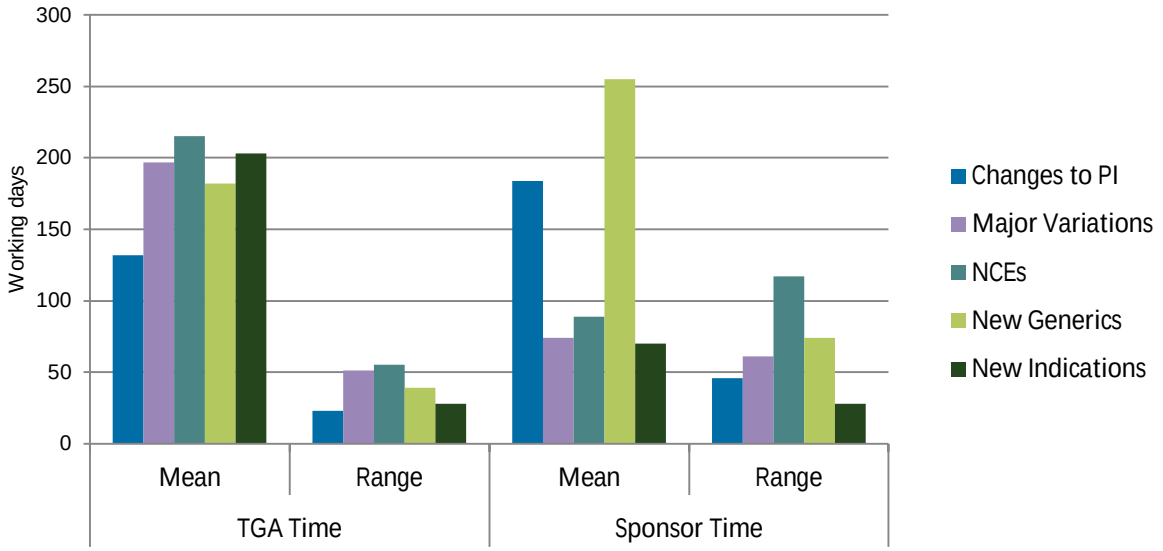
PI=Product Information.

Table 5 Outcomes of submissions

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Approved by delegate				
Category 1	168	208	178	166
Category 3	695	785	744	737
Sub-total	856	993	922	903
Rejected by delegate				
Category 1	4	5	9	1
Category 3	1	0	0	0
Sub-total	5	5	9	1
Withdrawn by Sponsor				
Category 1	19	17	19	7
Category 3	13	7	10	8
Sub-total	32	24	29	15
Rejected in application entry				
Category 1	0	0	0	0
Category 3	0	0	0	0
Sub-total	0	0	0	0
Total finalised submissions				
Category 1	191	230	206	174
Category 3	709	792	754	745
Total number of submissions	900	1022	960	919

1.1.2 Prescription medicines processing times

Figure 1 Processing times for Category 1 applications finalised: July to 31 December 2014



PI=Product Information; NCEs=New Chemical Entities.

Table 6 Mean processing times for Category 1 and Category 3 submissions (working days)

		2013		2014	
	Target	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Category 1 submissions					
Acceptance to evaluation completed	135	197*	198*	199*	135
Evaluation completed to delegate's decision	120	45	46	46	36
Net overall TGA evaluation time	255	177	178	178	171
Category 3 submissions					
Receipt and payment to acceptance	5	8	7	8	7
Acceptance to evaluation completed	30	16	20	19	18
Evaluation completed to delegate's decision	10	2	2	2	2
Net overall TGA evaluation time	45	29	28	30	26

* The previous periods also included the pre-submission processing times.

1.2 Over-the-counter medicines

The over-the-counter (OTC) application categorisation framework outlined below defines the different OTC medicine application levels and the key application criteria.

Table 7 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.

<https://www.tga.gov.au/publication/otc-application-categorisation-framework>

1.2.1 Performance during July to December 2014

Table 8 Summary of received, in progress and completed applications

Application category	Number received	Number completed[1]	Number in progress
N1	88	116	11
N2	8	8	0
N3	21	21	12
N4	45	58	37
N5	8	17	7
Sub-total	170	220	67
C1	255	261	21
C2	125	134	27
C3	2	3	2
C4	11	0	11
Sub-total	393	398	61
Total	563	618	128

[1]See Table 9 for details of the outcomes of these applications. In this context 'completed' means the delegate has made a decision or the application is no longer being processed because it was returned to the applicant as 'not valid' or 'not effective' or 'withdrawn'.

Table 9 Completed OTC applications by application category

	Outcome				
Application category	Returned	Withdrawn	Rejected	Approved	Total
N1	1	9	0	106	116
N2	0	0	0	8	8
N3	2	0	0	19	21
N4	7	5	0	46	58
N5	5	0	0	12	17
Percentage of N applications	7%	6%	0%	87%	100%
C1	0	4	0	257	261
C2	1	4	0	129	134
C3	0	0	0	3	3
C4	0	0	0	0	0
Percentage of C applications	0%	2%	0%	98%	100%
Total number of applications	16	22	0	580	618

Table 10 Processing times against target time by application category

		Elapsed working days[1]				
Application category	Number	Range	Mean	Median	Target time[2]	%within target
N1	106	1-52	30	31	45	94
N2	8	26-44	29	26	75	100
N3	19	6-101	51	43	150	100
N4	46	19-169	125	133	170	100
N5	12	89-137	123	137	210	100
C1	257	0-52	8	6	20	96
C2	129	0-107	16	10	64	99
C3	3	24-176	84	51	120	67[3]
C4	0	N/A	N/A	N/A	170	N/A
Total	580					

This table reports on performance undertakings made during the design of the new OTC premarket business processes. These are subject to ongoing review. As at 31 December 2014, the average processing times were well below the target.

N/A=Not applicable.

[1]Between acceptance of application to a formal notification of decision

[2]The target is 80% completed within the agreed timeframe.

[3] C3 applications were low in number and one of the three applications exceeded the target time due to atypical complexities.

1.2.2 Trend data – July 2013 to December 2014

The TGA has been undertaking a business process reform that has resulted in changes to the application categories, target times and a number of other elements. As a result more detail is available, but at this time not all data are available for the full 36 months.

Figure 2 Number of new applications received

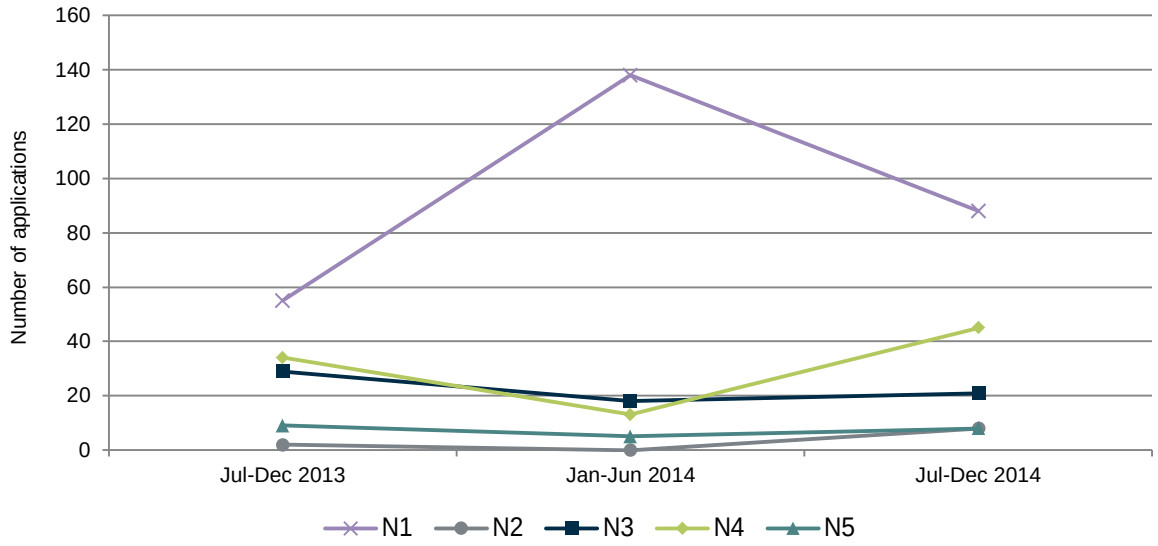


Figure 3 Number of change applications received

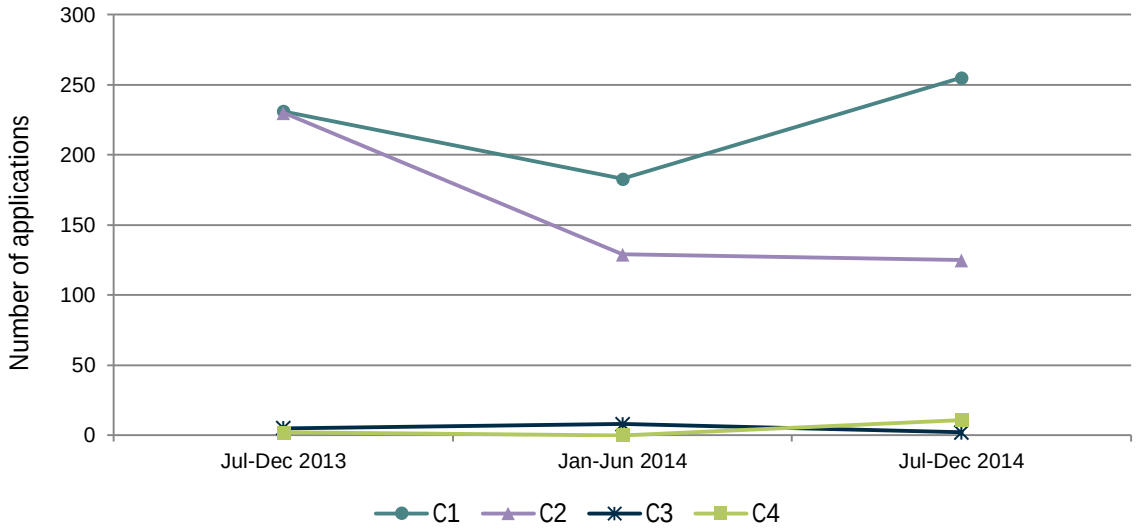


Table 11 New applications, notifications and variations applications received

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
New applications received			
N1	55	138	88
N2	2	0	8
N3	29	18	21
N4	34	13	45
N5	9	5	8
Total	129	174	170
Notifications and variations			
C1	231	183	255
C2	230	129	125
C3	5	8	2
C4	2	0	11
Total	468	320	393

1.2.2.1 Applications in progress

Table 12 Applications in progress (screening and evaluation)

	2013	2014	
	31 Dec	30 Jun[1]	31 Dec
New applications in progress			
N1	21	39	11
N2	2	0	0
N3	37	11	12
N4	51	49	37
N5	16	16	7
Total	127	91	67
Notifications and variations			
C1	19	26	21
C2	75	36	27
C3	5	5	2
C4	5	0	11
Total	104	43	61

[1]The number of in progress applications at the end of June 2014 stated in Table 8 of the Jan-Jun 2014 report did not include applications in screening. The in progress applications for June 2014 in this table have been corrected to include applications in both screening and evaluation.

1.2.2.2 Applications completed

Table 13 New, variation and notification applications

	2012	2013		2014	
Application category/decision	Jul-Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
New applications: N1–N5					
Total completed	184	187	97	212	220
Approved	137	172	86	189	191
Rejected	0	1	1	1	0
Withdrawn by sponsor	23	7	2	8	14
Returned to sponsor	24	7	8	14	15
Clone: N1					
Total completed			48	136	116
Approved			45	131	106
Rejected			0	0	0
Withdrawn by sponsor			3	5	9
Returned/failed screening			0	0	1
Other new: N2–N5					
Total completed			56	71	104
Approved			45	58	85
Rejected			0	0	0
Withdrawn by sponsor			3	3	5
Returned/failed screening			8	10	14
Variations: C2–C4					
Total completed	N/A	N/A	176	179	137
Approved	182	129	176	178	132
Rejected	4	2	0	0	0
Withdrawn by sponsor	N/A	N/A	N/A	1	4
Returned/failed screening	0	0	0	0	1
Notifications: C1					
Approved/acknowledged	N/A	N/A	232	184	257
Rejected	N/A	N/A	0	0	0
Withdrawn by sponsor	N/A	N/A	16	7	4

N/A=not applicable.

1.2.2.3 Evaluation processing times

Table 14 Percentage within target time (payment of fees to delegate's decision)

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
New applications	%	%	%
N1	98	98	94
N2	100	100	100
N3	100	100	100
N4	N/A	100	100
N5	100	N/A	100
Variations			
C1	92	84	96
C2	100	98	99
C3	100	100	67
C4	N/A	100	N/A

N/A=not applicable.

Table 15 Average working days to decision (from acceptance of application)

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
New applications			
N1 = 45 working days	22	21	30
N2 = 75 working days	N/A	49	29
N3 = 150 working days	48	97	51
N4 = 170 working days	N/A	105	125
N5 = 210 working days	30	N/A	123
Variations			
C1 = 20 working days	13	16	8
C2 = 64 working days	22	40	16
C3 = 120 working days	35	33	84
C4 = 170 working days	N/A	69	N/A

The processing times achieved so far are well within TGA target times agreed during the design of the new OTC premarket business processes.

1.3 Export only medicines

1.3.1 New applications, variations and processing times

Table 16 New applications for export only medicines

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Applications received	175	70	83	60	65
Not accepted	0	0	0	0	0
Withdrawn	7	5	2	5	7
Approved	155	73	82	55	61
Rejected	0	0	0	0	0
Total completed	162	78	84	60	68
Total in progress at the end of the reporting period	26	18	17	17	14

Table 17 Variations and groupings for export only medicines

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Applications received	38	69	22	53	47
Not accepted	0	0	0	0	0
Withdrawn	6	1	0	1	2
Approved	40	74	22	52	39
Rejected	0	0	0	0	0
Total completed	46	75	22	53	41
Total in progress at the end of the reporting period	7	1	1	1	7

Table 18 Processing times for new applications and variations for export only medicines

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
New applications					
Average TGA processing time (working days)	27	27	24.8	23.8	20
Percentage processed within target timeframe (31 days)	74%	92%	80%	98%	100%
Average sponsor response time (working days)	2	11.3	5	8.6	6.8
Variations					
Average TGA processing time (working days)	31	24	24.7	21.6	12
Percentage processed within target timeframe (31 days)	88%	91%	90%	98%	100%
Average sponsor response time (working days)	0	7.5	0	0	0

Table 19 Processing times for applications in progress for export only medicines

	2012	2013		2014	
Time taken to date	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
0-4 weeks	74%	63%	50%	100%	71%
4-8 weeks	3%	11%	45%	0%	14%
8-12 weeks	0%	21%	0%	0%	5%
12-16 weeks	3%	0%	0%	0%	0%
>16 weeks	20%	5%	5%	0%	10%
Total number of applications received	213	139	105	113	112
Total incomplete at end of reporting period	33	19	18	18	21
Number awaiting response from sponsor	16	6	1	0	6

1.3.2 Export certifications for medicines

Table 20 Applications for export certifications

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Applications received	805	1044	954	1078	1146
Certificates issued	884	926	995	1093	1155
Applications rejected	0	0	0	0	0
Processing times					
From receipt of application to completion of finance processing (average number of working days)	1	1	1	1	1
From processing completed to issue of certificate (average number of working days)	11	12	12	11	11
Average TGA processing time (target 15 working days)	12	13	13	12	12
Percentage processed in less than 16 working days (target 100%)	99%	98%	96%	98%	99%

1.4 Complementary medicines

1.4.1 Registered complementary medicines

Table 21 Applications for registered complementary medicines

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Applications for new registered complementary medicines				
Applications received	2	0	1	1
Approved	1	1	0	3
Rejected	0	1	0	1
Withdrawn by sponsor	4	0	0	0
Lapsed	0	0	0	0
Total new applications on hand at 31 December 2014 = 3 [1]				
Applications for variations to registered complementary medicines				
Applications received	9	11	8	20
Approved	7	12	5	15
Rejected	1	0	0	1
Withdrawn by sponsor	0	0	0	0
Lapsed	0	0	0	0
Total variations applications on hand at 31 December 2014 = 9				

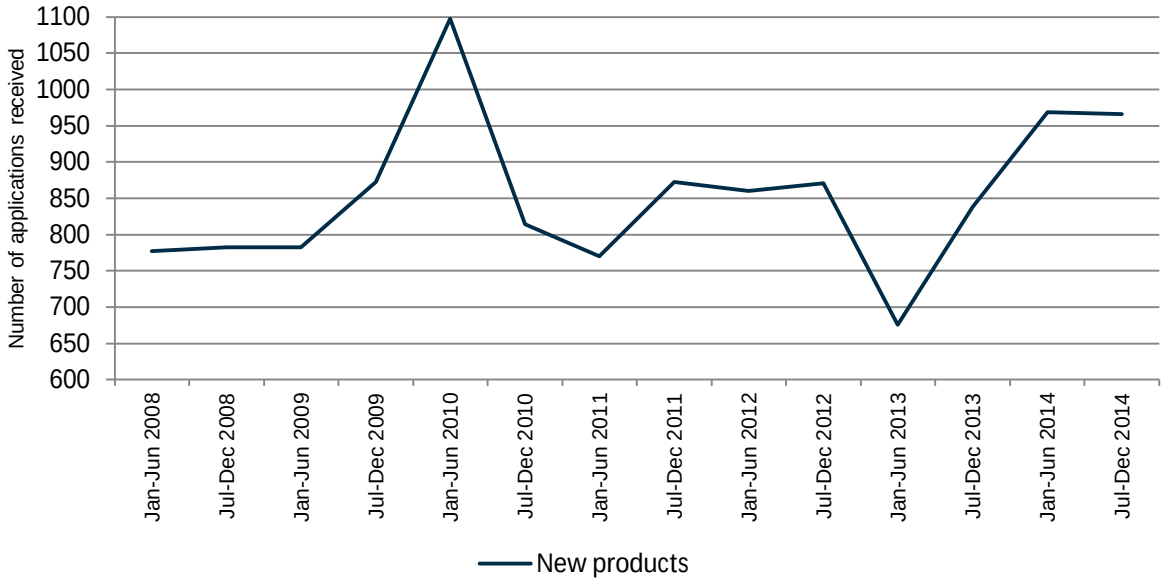
[1]Three of these active applications are different dosage forms of the same product line.

1.4.2 Listing of new ingredients and listing of new medicines for supply in Australia

Table 22 Applications for new listable substances (ingredients)

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Applications received	10	3	1	2
Approved	3	5	2	4
Rejected	1	1	4	0
Withdrawn by sponsor	0	1	0	0
Lapsed	0	0	0	0
Total applications on hand at 31 December 2014 = 4				

Figure 4 Applications received for new listed medicine products



These statistics include all listed complementary medicines and sunscreens.

Table 23 Number of listed medicines processed

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Medicines for supply in Australia				
New medicine entries	872	954	970	1022
Changes (major and minor)	784	853	604	596
Cancellations	958	207	1490	370
Total	2614	2014	3064	1988

1.5 Registration of biologicals

Table 24 Biologicals application workflow

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
Applications received			
Technical Master File (TMF) new	0	0	0
TMF annual updates	5	1	5
TMF variations	13	8	5
TMF notifications	10	4	5
Plasma Master File annual updates	13	12	6
Biological Class 2 – new applications	0	1	1
Biological Class 3 – new applications	0	0	0
Biological Class 2 – variations	0	0	2
Biological Class 3 – variations	3	4	1
Total	44	30	25
Applications completed			
Technical Master File (TMF) new	0	0	0
TMF annual updates	1	0	2
TMF variations	16	1	6
TMF notifications	9	1	5
Plasma Master File annual updates	7	6	9
Biological Class 2 – new applications	0	0	9
Biological Class 3 – new applications	0	0	4
Biological Class 2 – variations	0	0	1
Biological Class 3 – variations	1	3	0
Total	34	11	36
On hand at end of reporting period			
Technical Master File (TMF) new	2	2	2
TMF annual updates	5	4	4
TMF variations	1	7	0
TMF notifications	1	3	2
Plasma Master File annual updates	6	6	7
Biological Class 2 – new applications	19	20	11
Biological Class 3 – new applications	2	2	2
Biological Class 2 – variations	0	0	1
Biological Class 3 – variations	2	1	1
Total	38	45	30

For information about Biological Classes, see Australian Regulatory Guidelines for Biologicals[3].

1.6 Inclusion of medical devices

1.6.1 Medical devices application workflow

Table 25 Class 1 medical device application workflow

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Applications received	1439	886	1405	1302
Applications finalised	1439	1489	1397	1303

For explanation of Classes of Medical Devices, see Australian Regulatory Guidelines for Medical Devices[4]

Table 26 Class 1 measuring and sterile medical device application workflow

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Total Class 1 measuring and sterile medical devices				
Applications received	151	221	132	164
Applications completed	117	242	142	165
Applications on hand	117	81	49	10
Class 1 measuring medical devices				
Applications received	21	33	24	33
Applications completed	19	34	27	30
Applications on hand	17	13	7	3
Class 1 sterile medical devices				
Applications received	130	188	108	131
Applications completed	98	208	115	135
Applications on hand	110	68	42	7

[3] <https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb>
[4] <https://www.tga.gov.au/publication/australian-regulatory-guidelines-medical-devices-argmd>

Table 27 Class IIa and IIb medical device application workflow

	2013		2014	
	Jan-Jun	Jul-Dec	Jan-Jun	Jul-Dec
Class IIa medical devices				
Applications received	725	733	676	679
Applications completed	625	835	675	742
Applications on hand	455	356	226	58
Class IIb medical devices				
Applications received	298	336	350	357
Applications completed	276	365	339	375
Applications on hand	211	166	130	52

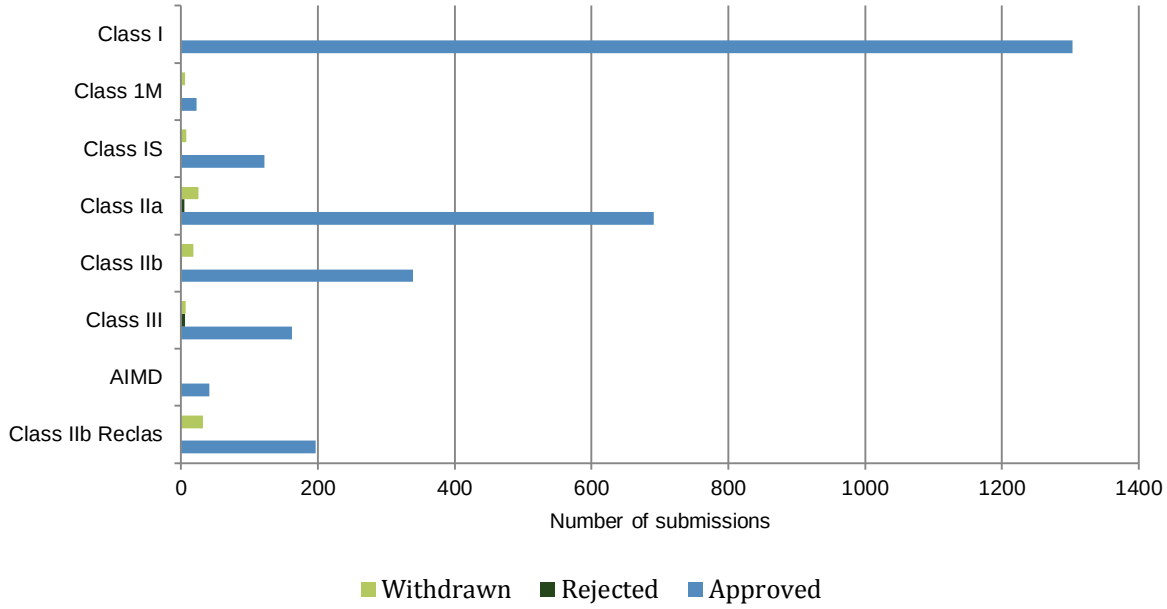
Table 28 Class III and AIMD medical device application workflow

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Total Class III, Class III Joint Reclassification and AIMDs				
Applications received	1256[1]	543	394	394
Applications completed	553[1]	555	640	457
Applications on hand	1014[1]	1628	1690	493
Class III medical devices				
Applications received	1021	271	219	243
Applications completed	379	194	262	184
Applications on hand	783	437	355	218
Class III Joint Reclassification medical devices				
Applications received	1015[1]	215	150	114
Applications completed	369[1]	329	329	231
Applications on hand	670[1]	1109	891	252
AIMD medical devices				
Applications received	64	57	25	37
Applications completed	44	32	49	42
Applications on hand	77	82	50	23

[1]The increase in applications received and applications on hand for the April to June quarter 2013 was due to the up classification of joint implants.

AIMD = Active Implantable Medical Device.

Figure 5 Outcomes of applications completed between July and December 2014



1.6.2 Medical devices processing times

Figure 6 Processing times for applications finalised (all medical devices): July to December 2014

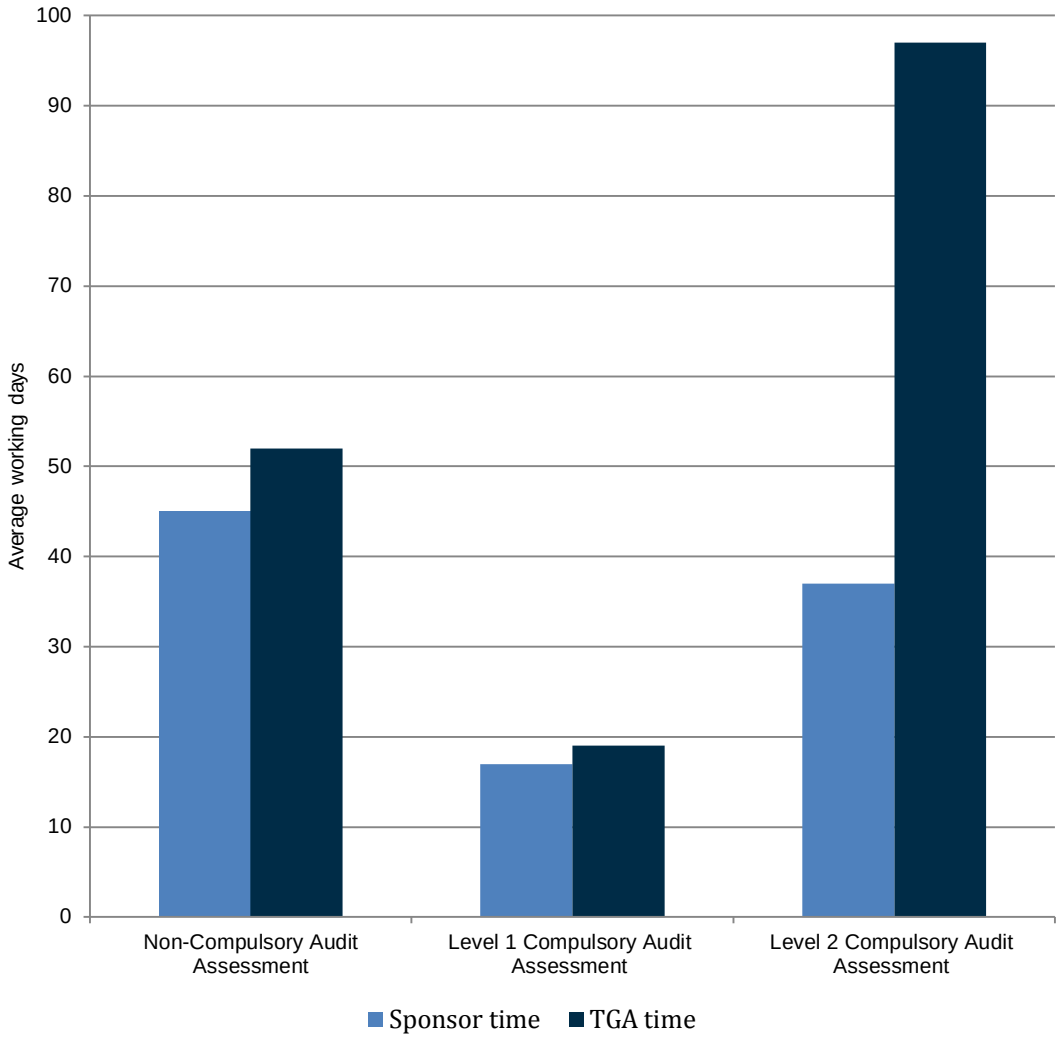


Table 29 Application audits of non-IVD medical devices completed: July to December 2014

	Percentage within target	Average TGA days
Level 1 Compulsory Audit Assessment (30 working day target)	77%	19
Level 2 Compulsory Audit Assessment (60 working day target)	18%	97
Non-Compulsory Audit Assessment (30 working day target)	54%	52

TGA received a high number of applications for ARTG inclusion for shoulder, knee and hip joint replacement devices during 2013. This had impact on resources allocation for audit assessments of other applications. Over the past 18 months, the number of outstanding application audits has gradually reduced for level 1 compulsory audit assessments and non-compulsory audit assessments.

1.7 Inclusion of in vitro diagnostic medical devices

1.7.1 IVD medical devices workflow

Table 30 IVD application workflow (all classes)

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Applications received	267	275	363	199
Applications completed	254	294	319	265
Applications on hand	88	48	126	23

Figure 7 IVD applications received by class

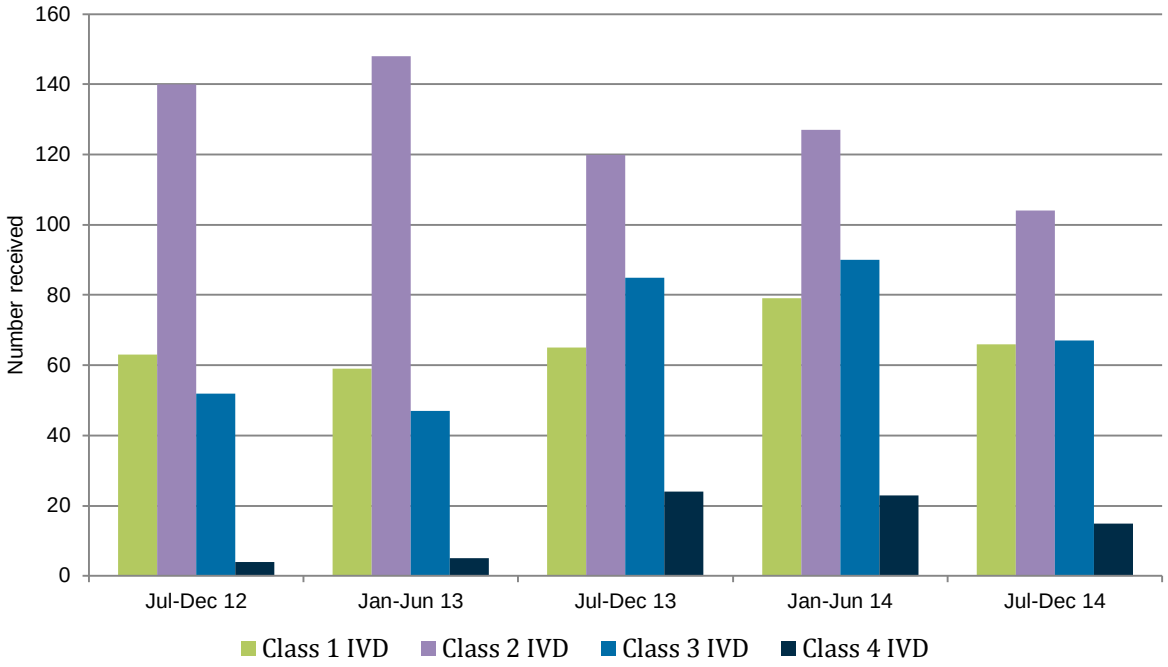
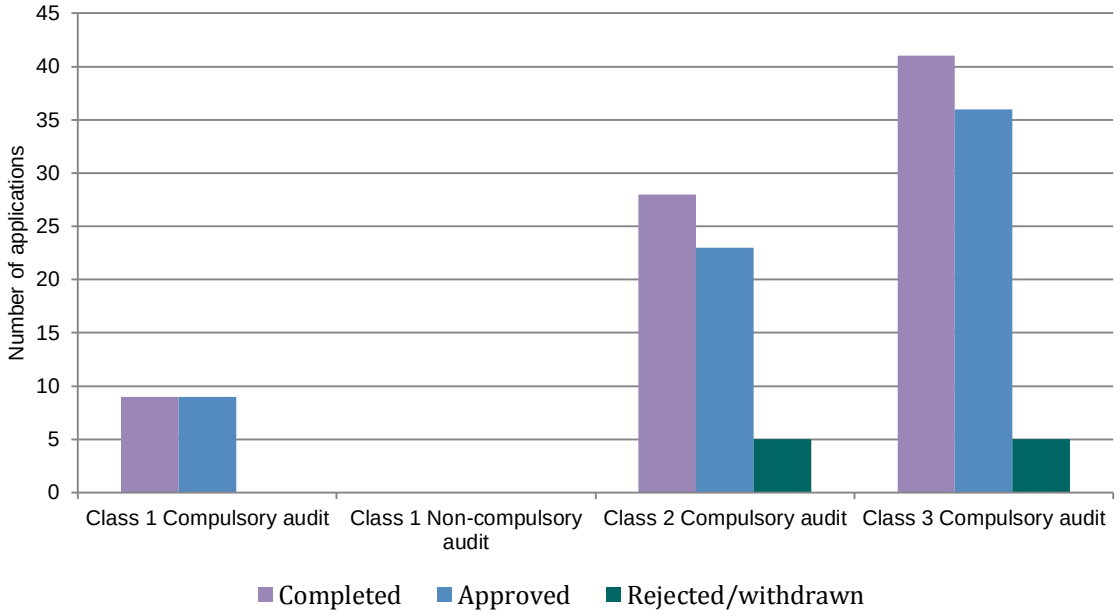


Table 31 Class 1 IVD application workflow and outcomes

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Class 1 IVDs				
Applications received	59	64	86	53
On hand	2	1	8	3
Completed	59	65	79	72
Approved	56	65	78	66
Rejected	0	0	0	0
Withdrawn	3	0	1	6
Class 2 IVDs				
Applications received	146	110	145	77
On hand	21	10	28	5
Completed	148	120	127	104
Approved	133	113	123	94
Rejected	1	0	1	1
Withdrawn	14	7	3	9
Class 3 IVDs				
Applications received	57	77	108	55
On hand	27	16	34	15
Completed	47	85	90	74
Approved	39	80	77	61
Rejected	0	0	1	2
Withdrawn	7	5	12	11
Class 4 IVDs				
Applications received	5	24	24	14
On hand	0	0	1	0
Completed	5	24	23	15
Approved	4	24	22	15
Rejected	0	0	0	0
Withdrawn	1	0	1	0
Totals				
Approved	228	282	300	236
Rejected	1	0	2	3
Withdrawn	24	12	17	26

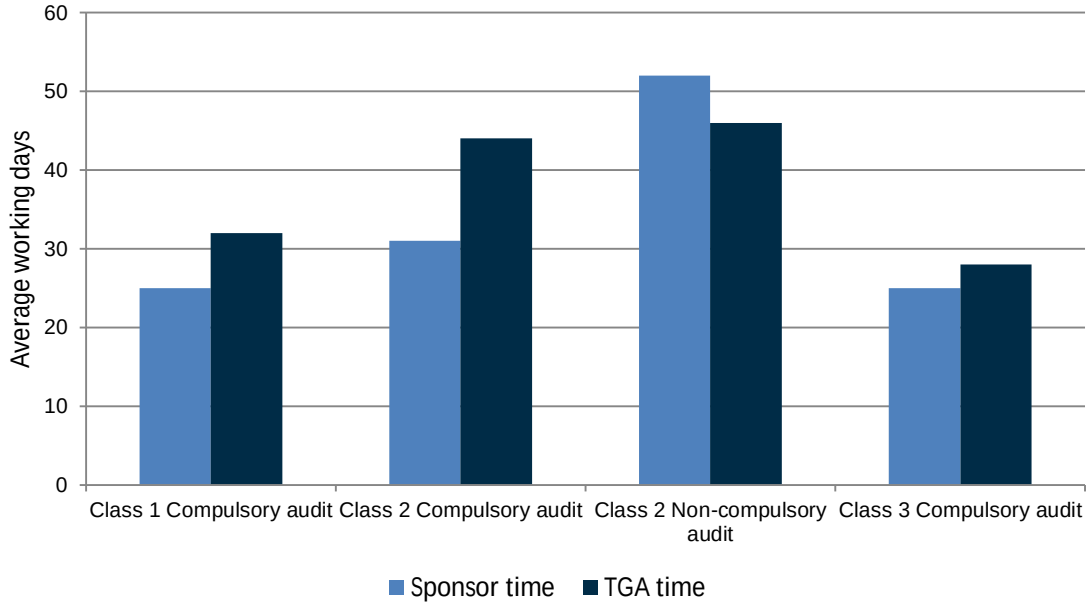
The figures for withdrawn applications only include those applications that were withdrawn after payment, not applications that were withdrawn prior to payment for the application.

Figure 8 Outcomes of IVD applications selected for application audit: July to December 2014



1.7.2 In vitro diagnostic medical device applications processing times

Figure 9 Processing times for IVD application audits: July to December 2014



1.8 Medical device conformity assessment applications

Table 32 Medical device (including IVD) conformity assessment applications

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Applications received	104	118	136	98	112
Applications completed	91	116	121	162	115
Applications on hand	178	180	195	131	125

Table 33 IVD conformity assessment application workflow

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Applications received	19	25	14	16
Applications completed	10	16	24	25
Applications on hand	67	79	68	22

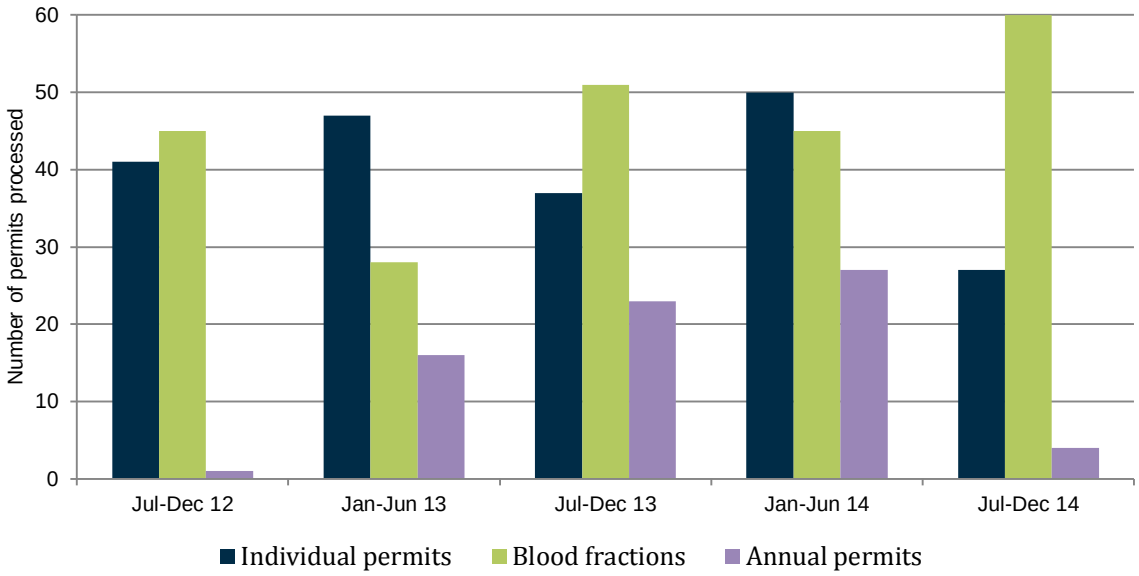
1.9 Export certifications for medical devices

Table 34 Applications for export certifications workflow

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Export Certification Assessments					
Applications received	161	228	152	222	239
Export certificates issued	151	206	161	198	255
Applications rejected/withdrawn	0	0	2	0	8
Average processing times (working days)					
Export certificates (target = 5 days)	5	4	3	3	3
Percentage processed within target time (Target >90%)	66%	89%	98%	98%	95%

1.10 Blood permits for export processed

Figure 10 Number of permits processed



1.11 Access to unapproved therapeutic goods

The TGA is in the process of transitioning to an electronic lodgement system for clinical trial notifications (CTN). In 2014, clinical trials that include medical devices have been processed using the same database as that for medicines and biologicals. The figures provided for 2014 combines reporting for biologicals, medicines and devices into a single table for notifications received by State or Territory (tables 36 and 39). Previously clinical trials involving medical devices and biologicals were reported in a separate subsection, this subsection now refers back to tables 36 and 39.

It should also be noted that for tables 37 and 40, the values for notifications categorised as “none specified” has increased as well as the final total values for 2014. This is because these values include data for devices.

1.11.1 Clinical trial notifications: medicines

Table 35 New trial notifications that include a medicine or biological received by State or Territory (single & multi-site trials)

	2012	2013	
	Jul–Dec	Jan–Jun	Jul–Dec
New South Wales	207	143	164
Victoria	122	110	106
Queensland	29	30	33
South Australia	38	25	41
Western Australia	20	18	10
Tasmania	0	0	1
Australian Capital Territory	0	0	0
Northern Territory	0	0	0
Total	416	326	355

Table 36 New trial notifications that include a therapeutic good (biological, device or medicine) received by State or Territory (single & multi-site trials)

	2014											
	Jan–Jun (total = 449)						Jul–Dec (total = 518)					
	M	D	B	M&D	D&B	M&B	M	D	B	M&D	D&B	M&B
New South Wales	123	30	1	72	0	0	97	35	1	113	0	0
Victoria	92	18	1	19	0	1	95	18	2	32	0	0
Queensland	26	4	1	8	1	0	47	4	2	3	1	0
South Australia	25	0	0	7	0	0	20	3	0	11	0	0
Western Australia	11	4	0	4	0	0	14	10	2	3	0	0
Tasmania	1	0	0	0	0	0	3	0	0	0	0	0
Australian Capital Territory	0	0	0	0	0	0	2	0	0	0	0	0
Northern Territory	0	0	0	0	0	0	0	0	0	0	0	0
Total	278	56	3	110	1	1	278	70	7	162	1	0

M=medicine, D=device, B=biological

Table 37 New trial notifications that include a therapeutic good (biological, device or medicine) received by phase (single & multi-site trial)

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Phase 1	85	65	132	68	83
Phase 2	128	86	102	130	124
Phase 3	155	131	70	153	198
Phase 4	34	28	32	32	34
Bioavailability/equivalence	5	4	5	2	3
None specified	9	12	14	64*	76*
Total	416	326	355	449*	518*

*this number now combines those CTNs which involve device(s)

Figure 11 Total notifications and new trial notifications that include a medicine or biological

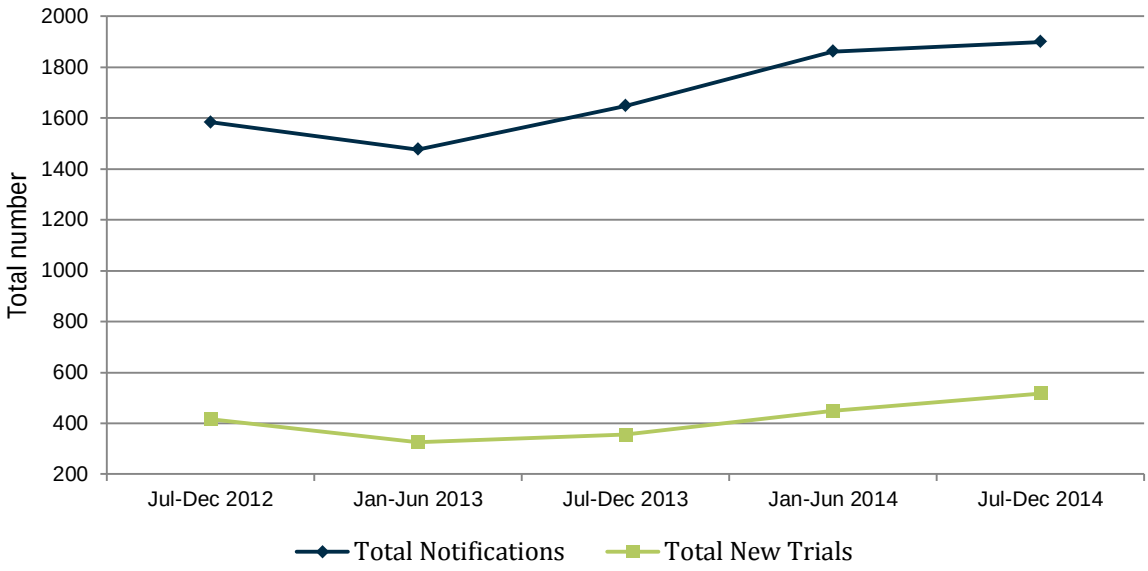


Table 38 Notifications that include a medicine or biological received by State or Territory (total number of trial sites notified)

	2012	2013	
	Jul–Dec	Jan–Jun	Jul–Dec
New South Wales	435	404	492
Victoria	460	415	507
Queensland	312	311	268
South Australia	165	168	193
Western Australia	151	125	123
Tasmania	28	29	31
Australian Capital Territory	29	25	33
Northern Territory	4	0	1
Total	1584	1477	1648

Table 39 All Notifications that include a therapeutic good (biological, device or medicine) received by State or Territory (single & multi-site trials)

	2014											
	Jan–Jun (total = 1862)						Jul–Dec (total = 1900)					
	M	D	B	M&D	D&B	M&B	M	D	B	M&D	D&B	M&B
New South Wales	601	93	6	376	0	0	297	36	1	191	1	0
Victoria	400	41	1	81	0	0	285	41	3	252	0	0
Queensland	86	4	0	49	1	0	209	11	4	140	0	0
South Australia	52	0	0	31	0	0	102	15	0	102	0	0
Western Australia	22	4	0	5	0	0	76	13	2	62	0	0
Tasmania	5	0	0	3	0	0	14	0	2	11	0	0
Australian Capital Territory	1	0	0	0	0	0	14	1	0	9	0	0
Northern Territory	0	0	0	0	0	0	5	0	0	1	0	0
Total	1167	142	7	545	1	0	1002	117	12	768	1	0

M=medicine, D=device, B=biological

Table 40 Notifications that include a therapeutic good (biological, device or medicine) received by phase (total number of trial sites notified)

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Phase 1	143	115	123	94	131
Phase 2	465	355	374	421	436
Phase 3	842	890	1020	978	1088
Phase 4	120	96	95	210	116
Bioavailability/equivalence	5	4	5	5	4
None specified	9	17	31	154*	125*
Total	1584	1477	1648	1862*	1900*

*this number now combines those CTNs which involve device(s)

1.11.2 Special access scheme

The Special Access Scheme 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. Patients are grouped into two categories under the scheme:

- Category A patients are defined as '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'.
- Category B patients are all other patients that do not fit the Category A definition.

Table 41 Category A notifications and Category B applications for medicines

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Total notifications (Category A)	19,795	15,790	19,259	17,648	18,698
Applications received (Category B)	8792	9036	12,938	10,027	10,631
Approved	8626	8681	12,557	9675	10,338
Cancelled	31	45	226	181	172
Rejected	30	53	13	22	47
Pending at end of reporting period	105	257	142	32	74

Table 42 Category A notifications and Category B applications for devices

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Total notifications (Category A)	1130	649	1561	1139	1968
Applications received (Category B)	1543	1143	1415	1257	1218
Approved	1542	1142	1408	1159	1121
Cancelled	0	1	5	11	75
Rejected	1	0	0	16	17
Pending at end of reporting period	0	0	2	65	5

Table 43 Category A notifications and Category B applications for biologicals

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Total notifications (Category A)	3	9	5	24	38
Applications received (Category B)	788	964	962	1171	1229
Approved	788	964	961	1135	1225
Rejected	0	0	0	4	1
Pending at end of reporting period	0	0	1	23	0

1.11.4 Authorised prescribers

Table 44 Authorised prescriber approvals for medicines and medical devices

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Number of approvals - medicines	402	251	221	213	324
Number of approvals – medical devices	116	141	101	88	129

1.11.5 Import permits

Table 45 Import permits issued for medicines under Regulation 5G and 5H of the Customs (Prohibited Imports) Regulations 1956

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Number of approvals	344	402	273	219	224

1.12 Orphan drug designations

Table 46 Number of orphan drug designations

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Number of designations	23	6	11	11	11

2. Postmarket activities

2.1 Licencing and manufacturing

2.1.1 Manufacturing licences

Table 47 Manufacturing licence applications

	2010–11	2011–12	2012–13	2013–14	Jul-Dec 14
New licences granted	23	13	19	22	4
Withdrawn application	9	2	7	39	21
Revoked licences - Voluntary	0	0	19	23	6
Revoked licences – TGA	0	0	1	0	0
Ceased	16	29	0	0	0
Suspended	1	4	3	1	0
Suspended – Voluntary	N/A	N/A	3	1	0
Suspended – TGA	N/A	N/A	0	0	0

As at 31 December 2014, there were 414 Australian companies holding manufacturing licences covering 457 sites.

N/A=Not applicable. The separate recording of voluntary and TGA suspension of licences commenced in 2012–13.

Figure 12 Licence application outcomes for July to December 2014

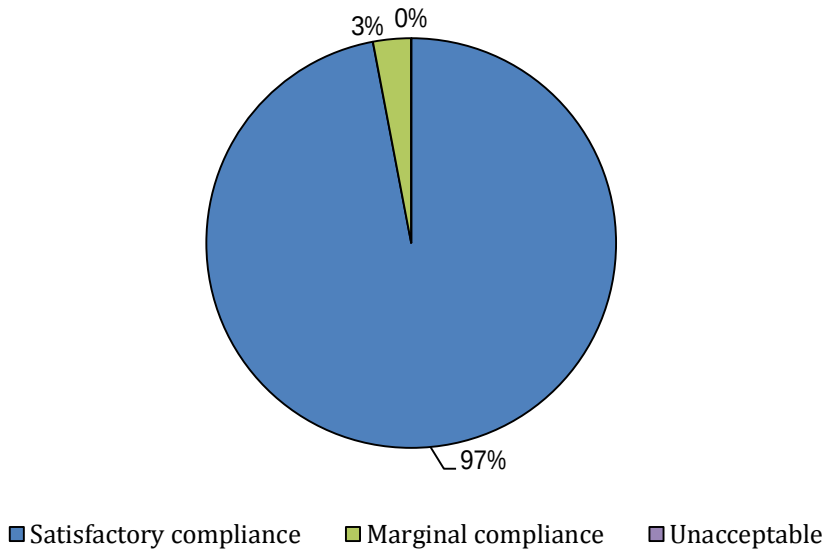


Table 48 Licence application outcomes

	2010–11	2011–12	2012–13	2013–14	Jul-Dec 14
Inspections conducted	244	272	247	201	102
Satisfactory compliance	76%	81%	85%	89%	97%
Marginal compliance	23%	16%	12%	10%	3%

	2010–11	2011–12	2012–13	2013–14	Jul-Dec 14
Unacceptable	1%	3%	3%	1%	0%
Initial inspections conducted within 3 months of application	81%	79%	60%	87%	56%
Re-inspections conducted within 6 months of due date	86%	68%	70%	64%	31%

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.

2.1.2 Manufacturing certifications

Table 49 Certification application status

	2010–11	2011–12	2012–13	2013–14	Jul-Dec 14
New applications received	189	141	117	153	38
Re-inspection applications	235	172	229	172	83
Certified	119	130	156	133	67
Rejected	0	0	111	82	39

As at 31 December 2014, there were 410 overseas manufacturers covering 422 manufacturing sites.

Figure 13 Certification outcomes for July to December 2014

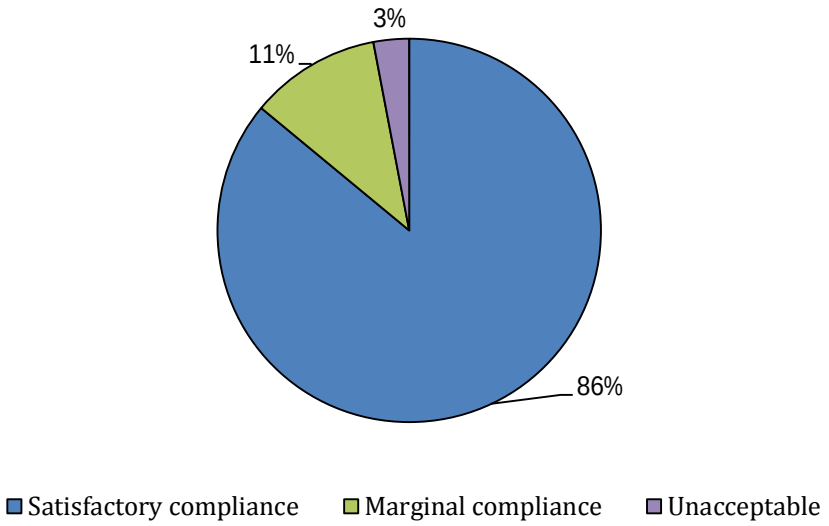


Table 50 Certification outcomes

	2010–11	2011–12	2012–13	2013–14	Jul-Dec 14
Inspections conducted	157	143	109	113	47
Satisfactory compliance	84%	87%	86%	93%	86%
Marginal compliance	14%	13%	13%	7%	11%
Unacceptable	2%	0%	1%	0%	3%

	2010–11	2011–12	2012–13	2013–14	Jul-Dec 14
Initial certifications inspections conducted within 6 months of application	90%	80%	74%	68%*	80%
Certification re-inspections conducted within 6 months of due date	75%	82%	68%	51%	44%

*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.

2.1.3 GMP clearances

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

Table 51 Clearance application status

	2010–11	2011–12	2012–13	2013–14	Jul-Dec 14
Applications received	2418	3900	3941	4222	1675
Renewal applications	1067	1172	1033	1218	730
Approved	3362	4103	3644	3539	1897
Rejected	18	232	92	73	224

Table 52 Clearance application outcomes

	2010–11	2011–12	2012–13	2013–14	Jul-Dec 14
Evidence from a country with an MRA[1] with Australia	1478	1444	1575	1500	621
Compliance Verification evidence[2]	520	283	316	299	130
TGA Certification	677	698	405	256	150

[1]MRA=Mutual Recognition Agreement between Australia and other countries, whereby the parties recognise and accept the certification issued by the relevant regulatory agency in each country in relation to manufacturers located within that country.

[2]Assessment of a recent GMP inspection report of the relevant overseas manufacturing site prepared by a competent overseas regulatory agency acceptable to the TGA, together with supporting manufacturing documentation supplied by the sponsor or manufacturer.

2.2 Laboratory testing

Table 53 Number of samples and products tested by TGA

		2012	2013		2014	
		Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Prescription medicines	Total	404	558	419	540	377
	% fail	1%	2%	2%	1%	1%
OTC medicines	Total	31	31	62	15	20
	% fail	10%	13%	3%	0%	40%
Complementary medicines	Total	54	71	42	200	77
	% fail	24%	24%	24%	27%	30%
Medical devices	Total	284	100	75	69	75
	% fail	21%	23%	17%	30%	19%
Contract[1]	Total	12	3	2	47	23
	% fail	25%	0%	0%	0%	22%
Unregistered[2]	Total	109	91	105	186	166
	% fail	62%	67%	64%	82%	54%
Total samples per half year[3]		1000	938	816	1289	1013
Total samples per half year (excluding AHQ samples)		895	855	705	1057	738
Percentage fail per half year		17%	13%	14%	22%	19.6%
Total number of products tested per half year[4]		488	394	385	507	403

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

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

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

[4]The TGA may test a number of samples of each product per reporting period.

Table 54 Laboratory testing: reason for failed samples, July to December 2014

	Medical devices	OTC medicines	Prescription medicines	Unregistered products	Comp medicines	Total
Contamination	5	0	1	3	1	10
Formulation	4	8	0	75	6	93
Label and packaging deficiencies	3	0	0	0	10	13
Performance	0	0	0	4	0	4
Physical or mechanical properties	2	0	4	8	6	20
Total	14	8	5	90	23	140

Table 55 Target timeframes for testing (working days)

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

Samples requiring biological testing are excluded from the target turnaround timeframes.

Table 56 Compliance with testing timeframes: July to December 2014

	Priority	Total	Percentage
Medical devices	Routine	122	78%
	Priority	18	94%
	Urgent	5	100%
OTC medicines	Routine	26	65%
	Priority	0	0%
	Urgent	0	0%
Prescription medicines	Routine	110	80%
	Priority	21	100%
	Urgent	0	0%
Complementary medicines	Routine	91	69%
	Priority	14	100%
	Urgent	2	50%
Unregistered products	Routine	67	69%
	Priority	98	96%
	Urgent	5	100%

Low numbers of samples in categories may affect compliance percentages.

Table 57 Batch release and export certification

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Batch release[1]	176	248	136	225	152
Export certification	26	75	23	36	5

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

2.3 Recalls

2.3.1 Medicine recalls

Table 58 Numbers of medicine recalls

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Recalls to consumer level	4	4	4	2	1
Recalls to hospital level	8	8	14	8	8
Recalls to retail level	9	5	5	7	10
Recalls to wholesale level	2	2	2	3	3
Total	23	19	25	20	22

Table 59 Medicine recalls: reason for recalls

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Adverse reactions	1	0	1	1	0
Foreign matter	0	1	1	0	3
Illegal supply	1	2	2	0	0
Impurity and degradation	0	1	0	3	3
Labelling and packaging	8	3	7	5	8
Micro-organisms	1	5	0	0	0
pH	0	0	0	0	0
Potency	0	1	1	1	1
Sterility	0	0	0	1	1
Other[1]	12	6	13	9	6
Total	23	19	25	20	22

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

2.3.2 Medical device and biological recalls

Table 60 Medical devices (including IVDs): numbers of recalls

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Recalls to consumer level	8	11	11	11	4
Recalls to hospital level	246	265	280	262	270
Recalls to retail level	32	21	11	12	17
Recalls to wholesale level	2	3	3	2	0
Total medical device recalls	288	300	305	287	291

Table 61 Medical devices (including IVDs): reason for recalls

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Adverse incidents	2	1	1	0	1
Diagnostic inaccuracy	46	46	37	29	38
Electrical defect	22	20	10	17	25
Illegal supply	5	0	0	0	0
Labelling and packaging	53	49	56	61	43
Mechanical and physical defects	97	119	125	100	96
Software defects	47	55	65	69	59
Sterility	2	0	1	2	5
Other[1]	14	10	10	9	24
Total	288	300	305	287	291

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

Table 62 Numbers of biologicals recalls

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Recalls to hospital level	0	7	0	2	0

2.4 Adverse medicine reaction reports

2.4.1 Incoming adverse medicine and vaccine reaction notifications

Figure 14 Total number of incoming adverse medicine reaction notifications received

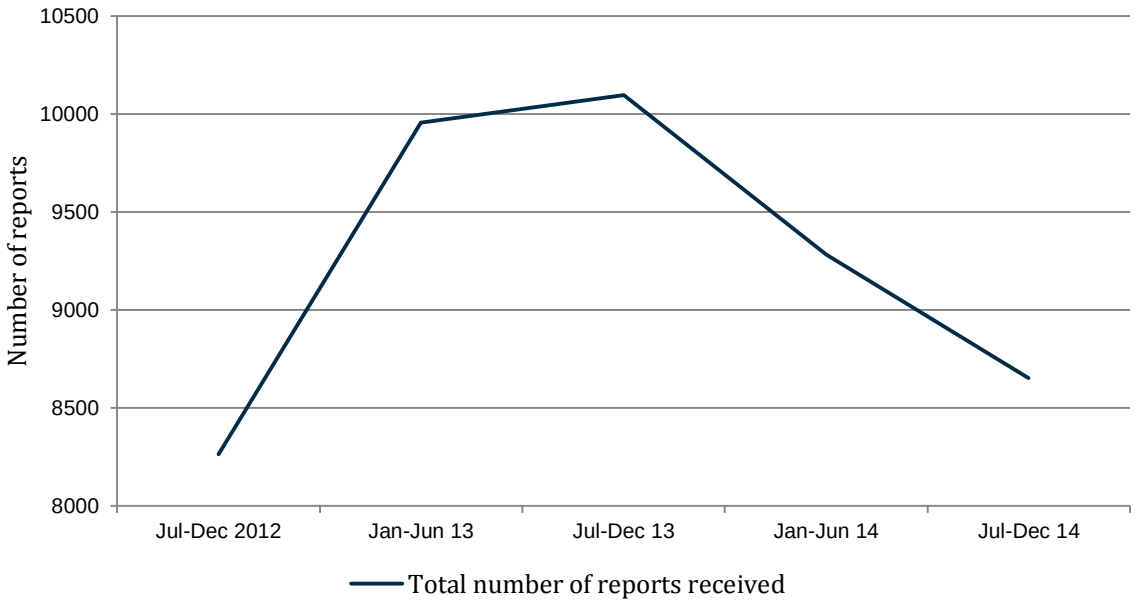


Table 63 Source of incoming notifications

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Hospitals	852	837	941	978	1205
Companies	4144	4499	5085	4183	4202
General Practitioners	349	372	357	397	340
Specialists	87	106	117	93	122
Pharmacists	552	562	717	630	594
Members of the Public (Consumer)	312	300	273	298	231
Nurses, dentists, complementary	90	99	76	117	113
State/Territory Health departments	757	1835	1276	1636	1048
General list (cause unclear) includes rejected and withdrawn	1121	1348	1256	952	797
Total	8264	9958	10098	9284	8652
Vaccine reports[1]	903	2125	1432	2008	1276
Average number of reports received weekly	317	383	388	357	332

[1]The data for vaccine reports comprise a subset of the total figure.

2.4.2 Communications and publications

Table 64 Communications and publications

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Requests for database output or other information	3388	4440	5570	6628	N/A[1]
1800 number calls received	286	312	204	113[2]	313
Public Contact Team (PCT)– Adverse reactions/events calls received	N/A	N/A	175	176	172
Medicines Safety Update (MSU) bulletin numbers	4, 5 ,6	7, 8, 9	10, 11, 12	13, 14, 15	16, 17, 18

[1]This figure is not reportable due to a change in email systems in this reporting period.

[2]This figure represents the calls about adverse events received to 1800 044 114 from Health professionals, consumers, manufacturers and sponsors. This service was taken over by AAPT from Telstra in late 2013 and due to the change-over the data for January to March 2014 was not recorded.

2.4.2.1 Medicines Safety Updates (MSU): July to December 2014

Medicines Safety Updates[5] are medicines safety bulletins issued six times yearly by the TGA. Three editions were published during the current reporting period.

[5] <https://www.tga.gov.au/publication/medicines-safety-update>

Early warning system: July to December 2014

The TGA's Early Warning System[6] provides current and historical information on safety concerns for medicines and medical devices (also known as therapeutic products) that the TGA has identified through its therapeutic product vigilance program. Early warnings were issued on the following medicines between July to December 2014:

No Early warnings were issued for the period July to December 2014.

Medicine alerts: July to December 2014

Alerts provided by the TGA contain important information and recommendations about therapeutic products. Even though an alert has been issued, it does not necessarily mean a product is considered to be unsafe. The following medicine alerts were published between July and December 2014:

- Galantamine
- Meningitec meningococcal serogroup C conjugate vaccine suspension for injection, single dose syringe
- Children's Panadol 1-5 years Colourfree Suspension
- Non-steroidal anti-inflammatory drugs and diclofenac reviews
- Serotonin-blocking medicines used to treat nausea and vomiting
- Propofol: Provive and Sandoz propofol 1% emulsion for injection – all sizes and all batches

2.5 Medical device incident reports

Table 65 Number of medical device incident reports received by financial year

	2009–10	2010–11	2011–12	2012–13	2013–14
Total received	1861	2161	2346	3013	3051
User reports	537	480	492	898	458
Sponsor reports	1324	1681	1854	2115	2593

Table 66 Australian incident notification workflow

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Reports entered	1271	1255	1630	1498	1662
Reports completed	1148	1865	1443	1578	2641
Reports still in progress	970	687	627	498	169

[6] <https://www.tga.gov.au/early-warning-system>

Table 67 Australian incident notification: processing times

		2012	2013		2014	
	Target	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Mean time to investigate and resolve	90 days	34	N/A	30	59	19
Percentage of reports not resolved in target time	0%	25%	N/A	16%	18%	14%

N/A = not applicable. Data unavailable due to system recording failure.

Table 68 Device incident notification report outcomes

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Reviewed and used for trend analysis purposes	459	516	736	862	1801
Reviewed, no further action required	284	754	585	583	689
Product Recall	23	29	37	42	23
Recall for Product Correction	6	10	37	18	5
Hazard Alert	1	55	41	36	40
Product Notification	1	0	1	0	1
Safety Alert	5	4	11	46	11
Product Enhancement/Improvement Notice	1	2	1	1	1
Instructions for Use Amended	9	10	28	26	15
Referral for Post-Market Review	1	2	1	2	53
Referral to TGA Office of Manufacturing Quality	1	3	0	9	1
Refer to another TGA Office	13	26	28	35	28
Company warned	0	0	1	3	0
Product Suspended from ARTG	0	1	0	0	0
Product Cancelled from ARTG	3	26	5	1	1
Manufacturing Process Improvements	22	30	18	42	11
Quality System Process Improvements	3	1	6	5	8
Maintenance Carried out by the Hospital	0	1	1	1	0
Change to Design	12	26	8	6	11
Not Device Related	26	8	11	9	6
Other	20	43	44	97	119

2.6 Listed medicine reviews

Table 69 New and completed reviews

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
New reviews/investigations initiated					
Targeted reviews	102	46	58	47	21
Random	2	4	19	22	13
Investigations[1]	22	42	7	49	38
Total	126	92	84	118	72
Reviews/investigations finalised					
Targeted reviews	116	48	77	68	113
Random	27	14	6	21	20
Investigations[1]	38	22	23	32	46
Total	181	84	106	121	179
Reviews in progress as at last day of each 6 monthly period	190	200	271	178	86

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

[1]Investigations can include products not listed on the ARTG.

Table 70 Listing compliance review outcomes

	Jul–Dec 2014	
	Number	Percentage
No compliance breaches identified against selected listing requirements	23	17%
Medicines with verified compliance breaches against selected listing requirements	80	60%
Compliance status not determined (Includes medicines cancelled after Section 31 notice issued, medicines not yet manufactured, financial cancellations etc.)	30	23%
Total	133	100%

Table 71 Listing compliance review issues

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
Information provided in ARTG entry	6	4	3
Product: formulation/manufacturing/quality	4	8	6
Labelling and Advertising	40	49	34
Evidence	10	14	25
Other (e.g. Sponsor has failed to comply with a condition that the medicine is subject to; Sponsor has failed to comply with an additional condition of listing, etc.)	9	6	40

Individual listings may have multiple issues and actions.

Table 72 Actions taken for listed medicines

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
Proposal to Cancel letter sent by the TGA	41	39	75
Medicines cancelled by TGA	7	6	45
Medicines cancelled by Sponsor after Proposal to Cancel letter issued	13	25	11
Medicines cancelled by Sponsor before compliance status could be determined e.g. after a section 31 notice was issued to Sponsor	6	18	18
Compliance reviews initiated but not able to be completed (e.g. medicine not yet manufactured or product cancelled for non - payment of fees)	9	10	13
Investigations resulting in initiation of target review	4	9	34

Individual listings may have multiple issues and actions.

2.7 Medical device postmarket reviews

Table 73 Devices verification: restricted word and targeted review workflow

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Restricted word reviews				
Reviews completed	25	27	17	7
Reviews commenced	17	20	17	4
Reviews on hand	16	14	13	0
Targeted reviews				
Reviews completed	101	63	114	94
Reviews commenced	41	83	136	33
Reviews on hand	151	320	413	67

2.8 Regulatory compliance

Table 74 Numbers of alleged offences

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
Import	379	325	380
Supply	195	217	177
Manufacture	10	9	5
Claims	5	5	12
Export	2	2	2
Total	591	558	576

Table 75 Categorisation of final action taken

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
Investigation in progress	222	257	168
Warned	223	371	291
No offence detected	90	100	82
Goods released under Personal Import Scheme	31	33	29
Referred to another agency or department outside of TGA	17	8	5
Referred to another Office within the TGA	7	8	1
Import treated as abandoned goods by Customs	1	0	0
Recall of goods	0	2	0
Matters referred to the Commonwealth Director of Public Prosecutions	0	3	0
Total	591	782	576

Table 76 Numbers of dosage forms investigated

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
Capsule	279	236	172
Tablet	214	263	260
Topical	149	97	99
Medical device	124	97	82
Injection	65	87	78
Oral liquid	36	23	24
Drops	19	7	1
Spray	13	5	14
Powder	12	20	24
Oral jelly/paste	11	17	19
Inhalator	3	2	0
Lozenge	3	2	0
Transdermal	2	2	1
Oral food	1	2	1
Reagent Test Kit	1	0	0
Other	0	6	0
Total	932	866	775

Table 77 Types of products investigated

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
Complementary medicines	390	421	260
Prescription medicines	349	318	383
Medical devices	121	100	81
Homoeopathic medicines	41	1	2
OTC medicines	17	9	32
Biological products	0	0	5
Other	17	18	14
Total	935	867	777

Table 78 Numbers of special interest investigations for each type

	2013	2014	
	Jul–Dec	Jan–Jun	Jul–Dec
Unapproved product	770	678	677
Counterfeit	137	172	92
Parallel import/export	4	2	0
Manufacture without licence	2	1	0
Advertising offence	0	0	1
Traditional Chinese medicines	0	0	1
Other	5	6	2
Total	918	859	773

Table 79 Numbers of investigations by complainant type and state/territory

Origin	ACT	NSW	NT	QLD	SA	VIC	WA	Others	Total
Complaints resolution	3	1	0	2	1	1	1	1	10
Customs	0	128	7	69	3	99	32	1	339
External agency	2	10	0	8	1	3	0	1	25
General public	0	15	0	4	4	4	2	100	129
Patient/practitioner	0	0	0	0	0	1	0	2	3
Sponsor/client	0	3	0	0	0	1	1	6	11
TGA internal	54	0	0	0	0	1	0	0	55
Total	59	157	7	83	9	110	36	111	572

3. Australian Register of Therapeutic Goods (ARTG)

3.1 New, variations and cancelled records

Table 80 Number of medicine registrations processed

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Prescription medicines					
New medicine entries	958	814	1013	847	815
Changes (major and minor)	7554	7439	9979	9183	9070
Cancellations	86	332	77	305	87
OTC medicines					
New medicine entries	140	159	89	177	198
Changes (major and minor)	182	129	176	178	132
Cancellations	13	146	9	107	30
Complementary medicines					
New medicine entries	1	1	1	0	3
Changes (major and minor)	8	7	12	5	15
Cancellations	1	6	0	17	37

Table 81 Number of listings processed

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Medicines for supply in Australia					
New medicine entries	875	872	954	970	1022
Changes (major and minor)*	783	784	853	604	596
Cancellations	382	958	207	1490	370
Medicines for export only					
New medicine entries	155	81	76	54	63
Changes (major and minor)	40	74	22	52	39
Cancellations	143	98	19	98	17

*These figures have been revised from the previous report as there were calculation errors

Table 82 Number of medical device inclusions processed

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Included medical devices					
New entries	2584	2863	3284	2961	2863
Cancellations	482	1752	639	2649	688
Included medical devices for export					
New entries	115	95	170	198	366
Cancellations	20	32	42	37	12
Included IVD medical devices					
New entries	233	228	267	283	220
Cancellations	8	6	8	8	11
Included IVD medical devices for export					
New entries	4	4	5	1	0
Cancellations	1	2	0	0	0
Other therapeutic goods					
New entries	9	12	18	10	12
Cancellations	11	38	18	84	33
Other therapeutic goods for export					
New entries	0	0	0	0	0
Cancellations	0	0	0	0	0

Table 83 Number of biological inclusions processed

	2013		2014	
	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
New entries	1	1	0	13
Cancellations	0	0	0	0

Table 84 Cancellation of registered and listed devices

	2012	2013		2014	
	Jul–Dec	Jan–Jun	Jul–Dec	Jan–Jun	Jul–Dec
Registered devices	0	0	0	0	0
Listed devices for supply in Australia	2	6	1	3	1
Listed devices for export only	0	0	0	0	0

3.2 ARTG product entries

Figure 15 Total number of product entries on the ARTG at end of reporting period

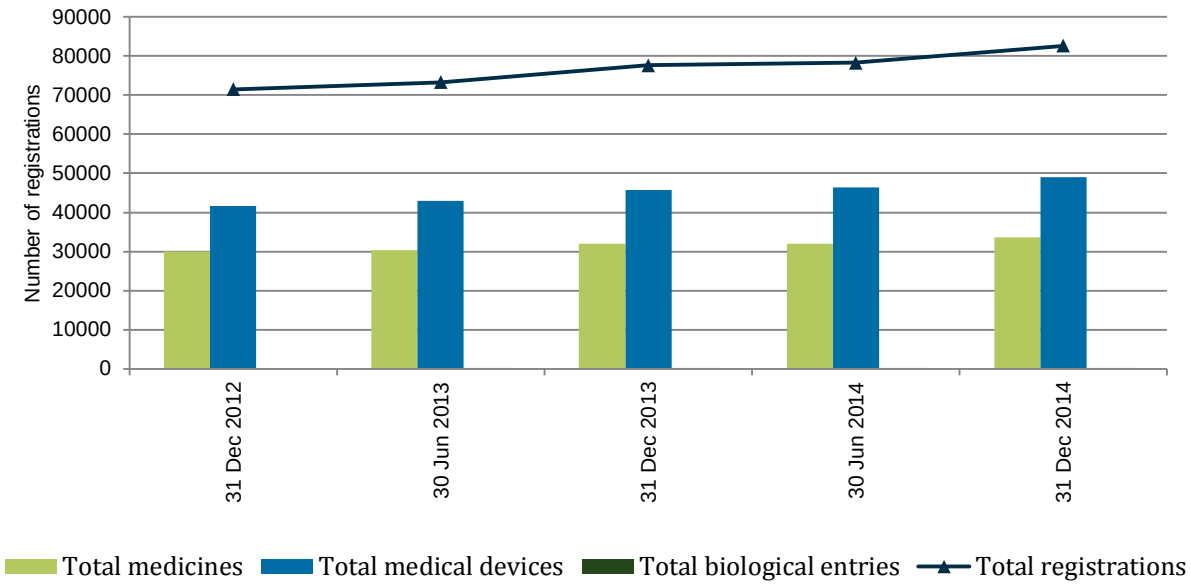


Table 85 Number of medicine entries on the ARTG

	2012	2013		2014	
	31 Dec	30 Jun	31 Dec	30 Jun	31 Dec
Medicine registrations					
Prescription medicines	12,316	12,792	13,720	14,259	14,990
OTC medicines	3193	3096	3177	3249	3419
Complementary medicines	91	198	193	175	141
Total registered medicines	15,600	16,086	17,090	17,683	18,550
Medicine listings					
Listed medicines	11,697	11,604	12,164	11,647	12,301
Export only medicines	2667	2650	2706	2662	2708
Total medicines	29,964	30,340	31,960	31,992	33,559

Table 86 Number of medical device entries on the ARTG

	2012	2013		2014	
	31 Dec	30 Jun	31 Dec	30 Jun	31Dec
Medical device inclusions					
Included devices	39,478	40,574	42,917	43,219	45,400
Included IVDs	724	946	1205	1480	1689
Included devices for export only	722	778	906	1067	1421
Included IVDs for export only	12	14	19	23	23
Other therapeutic goods					
Other therapeutic goods – listings and registrations	630	605	597	523	504
Other therapeutic goods for export only	10	10	10	10	10
Total medical devices	41,576	42927	45654	46,322	49,047

Table 87 Number of biological entries on the ARTG

	2013		2014	
	30 Jun	31 Dec	30 Jun	31 Dec
Biologicals	1	2	2	15

Table 88 ARTG totals

	2012	2013		2014	
	31 Dec	30 Jun	31 Dec	30 Jun	31 Dec
Total registrations on the ARTG	71,540	73,289	77,617	78,316	82,621
Total number of sponsors	3443	3565	3639	3673	3833

4. Abbreviations

ACPM Advisory Committee on Prescription Medicines

AIMD Active Implantable Medical Device

ARTG Australian Register of Therapeutic Goods

GMP Good Manufacturing Practice

IVD In vitro diagnostic medical devices

MRA Mutual Recognition Agreement

MSU Medicines Safety Update

OLSS Office of Laboratories and Scientific Services

OTC Over-the-counter

PI Product Information

PIP Poly Implant Prothese

PMF Plasma Master File

TMF Technical Master File

WHO World Health Organisation

5. Management of data from manual sources

Some of the data used in this report is initially drawn from manual record keeping systems and is reported prior to comprehensive verification. The verification process occasionally identifies errors in the original data. Where such errors are immaterial, the accurate comparative data will be reported in the next half-yearly report without being highlighted. Material or significant changes in comparative data will be reported in the next report and will include an explanatory note explaining the reason for the change.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
http://www.tga.gov.au

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