Australian Government
Department of Health
Therapeutic Goods Administration

# Annual Performance Statistics Report

## July 2016 to June 2017

# Contents

# About the Therapeutic Goods Administration

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

Products for which therapeutic claims are made are assessed by the TGA and entered on the Australian Register of Therapeutic Goods (ARTG). At 30 June 2017 there were 87,258 therapeutic goods on the ARTG. These therapeutic goods can be lawfully manufactured and supplied in Australia and include prescription medicines, over-the-counter medicines, complementary medicines, biologicals, and medical devices.

The TGA regulates the supply of:

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

We also play a regulatory role in overseeing the manufacturing process and advertising of therapeutic goods.

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

# Executive summary

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

The following statistics cover the period 1 July 2016 to 30 June 2017 and contribute to our suite of performance reports.

# Performance highlights: July 2016 to June 2017

Key observations for 2016-17 are summarised below, including trends and notable changes from previous reporting periods.

## Prescription medicines

Since the 2015-16 report, the number of submissions received across some Category 1 application types varied significantly. While the number of New Chemical Entity submissions remained constant, the number of Extension of Indication submissions increased noticeably and the number of generic medicine submissions greatly decreased. All Category 1 submissions processed in 2016-17 were within the legislated 255 working day timeframe and, on average, were decided in 220 working days or less.

## Over-the-Counter medicines

The total number of new medicine applications received in 2016-17 was slightly higher than in 2015-16 with an increase in the number of low risk (N1) and medium risk (N3) applications. In the higher risk (N4 and N5) categories, applications received in 2016-17 were roughly half that received in 2015-16. The total number of applications received to vary existing medicines decreased substantially compared with 2015-16, mostly due to a decrease in the number of low risk (C1) applications. The number of higher risk variation (C2, C3 and C4) applications was consistent with previous periods.

While median approval times for new medicine applications in 2016-17 were longer by approximately 2 weeks compared with 2015-16, the percentage of applications processed within target time continued to be at, or very close to 100%. The longer median approval times can be attributed to the increase in the number of lower risk and medium risk applications as well as varying level of complexity of higher risk applications.

## Complementary medicines

The number of new ingredients approved for use in listed medicines significantly increased to 79 in 2016-17 compared with 18 in 2015-16, primarily due to a number of excipient ingredients with limited availability being added to the Therapeutic Goods (Permissible Ingredients) Determination under section 26BB of the *Therapeutic Goods Act 1989*.

The number of post market compliance reviews completed has remained similar with 10% more reviews completed in 2016-17 than in 2015-16. Investigations, which arise from complaints from the public, industry referrals and adverse event reporting, increased in 2016-17 compared with 2015-16. Investigations are assessed using a risk prioritisation system and where required, will result in a compliance review being initiated.

The rate of verified compliance breaches has remained similar; 79% in 2016-17 compared with 80% in 2015-16. This suggests that the significant increase in the number of compliance reviews in recent years has not driven any improvement in compliance rates. The proportion of medicines found to be non-compliant for which breaches included 'insufficient evidence being held by the sponsor to support the medicine indication' was similar; 54% in 2016-17 compared with 64% in 2015-16.

Labelling, advertising and evidence continued to be major compliance breaches for listed medicines. In 2016-17, 22 products were found to have safety related issues, compared with 13 products in 2015-16. This increase was largely a result of continued targeted work undertaken on reviewing the safety of ingredients.

The number of approved new registered complementary medicines increased to 10 in 2016-17 compared with 3 in 2015-16. The total number of variations completed in 2016-17 decreased to 24 compared with 30 in 2015-16.

## Biologicals

The number of new and variation applications stabilised following the transition of most biologicals into the new biologicals regulatory framework during 2014-15. The number of Technical Master File variations increased due to work by the public cord blood banks.

## Medicine and vaccine adverse event reports

Overall, adverse event reporting increased from 17,633 medicine and vaccine adverse event notifications in 2015-16 to 19,736 in 2016-17. In particular, the increased number of vaccine Adverse Event Reports may reflect recent additions to the National Immunisation Program in 2016. Adverse event reporting from members of the public also increased which is likely to be the result of activity to promote consumer adverse event reporting.

## Medical device incident reports

An increase in incident reports in 2016-17 resulted from media attention, sponsor training workshops in 2016 to increase awareness, and expansion of the Insite program.

## Medical devices

There was a significant increase in the number of Level 2 compulsory audits of applications for inclusion of Class III and Active Implantable Medical Devices on the ARTG, which include the assessment of clinical evidence, completed in 2016-17 (471) compared with 2015-16 (205). We refined our processes for clinical evidence assessment in relation to audits and built the capability of our assessment teams to improve assessment timeframes for new medical devices. Concurrent assessments by staff with differing expertise, triage of applications and better application of the risk based approach to assessment of evidence for different categories of devices resulted in reduced waiting times for commencement of the audits of applications seeking pre-market authorisation from 8-9 months to about one month. By the end of the reporting period this significantly increased the completion rate of assessments and improved patients' access to new medical devices.

## Exports

The number of new export medicine listing applications and variations remained constant over the last two years. The number of export certificates for medicines dropped in 2016-17 by 25%, however there was an increase in the number of device certificates issued. All medicine certificates were issued within the target timeframe of 15 days. Over 80% of device certificates and new listings and variations were also completed within the target timeframe.

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

## Access to unapproved therapeutic goods

The number of notifications and applications for most Special Access Scheme (SAS) categories increased since 2015-16, especially Category A for both medicines and devices. An exception is SAS Category B for biologicals as higher volume products previously accessed through SAS are now on the ARTG.

## Medicines and biologicals manufacturing

Demand for Good Manufacturing Practice (GMP) clearances continued to increase with 6,506 applications received during 2016-17 compared with 5,657 in 2015-16. Major contributing factors included sponsors sourcing more products from new and multiple manufacturers, globalisation and company mergers, and overseas regulatory agencies undertaking more inspections in other countries, creating more evidence to be used in support of Australian GMP clearance applications.

## Recalls

There was a significant decrease in the number of medicine recalls from 57 in 2015-16 to 32 in 2016-17, and a slight decrease from 611 in 2015-16 to 598 in 2016-17 in the number of medical device recalls.

## Laboratory testing

Over the past four years there has been a continued increase in the failure rate of products tested by the TGA Laboratories on a contract basis for external agencies such as the World Health Organization (WHO) and other governments within the region. This increase was again observed in 2016-17. These results highlight the important role we play in supporting other governments to identify sub-standard, degraded or adulterated medicines supplied for use in other countries, and helping to ensure continued health security for the region, including Australia.

## Regulatory compliance

Investigations increased by 64% in 2016-17, with 2,887 completed compared with 1,760 in 2015-16. The largest contributor to investigations continues to be referrals from Australian Border Force in relation to the importation of unapproved prescription medicines.

# 1. Prescription medicines

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

The framework for prescription medicines includes the following categories which are subject to legislated 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. For example, 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: An application 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. For example, a change in the site of manufacture, a change to the synthetic route, a change in the product specifications, a change in the steps of manufacture or a change in trade name.

  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 application approval time for July 2016 to June 2017

| | | | Approval time (TGA working days) | | |
|---|---|---|---|---|---|
| Application type | Submissions approved | Legislated timeframe | Mean | Median | Range |
| A: New chemical entity | | | | | |
| Category 1 | 38 | 255 | 220 | 208 | 161-238 |
| B: New fixed-dose combination | | | | | |
| Category 1 | 4 | 255 | 201 | 203 | 179-218 |
| C: Extension of indication | | | | | |
| Category 1 | 45 | 255 | 198 | 202 | 106-238 |
| D: New generic medicine | | | | | |
| Category 1 | 111 | 255 | 182 | 172 | 109-254 |
| E: Additional trade name (ATN) | | | | | |
| Category 1 | 2 | 255 | 140 | 140 | 44-237 |
| ATN | 47 | 45 | 34 | 36 | 10-62 |
| F: Major variation | | | | | |
| Category 1 | 46 | 255 | 185 | 185 | 134-226 |
| G: Minor variation | | | | | |
| Category 1 | 0 | 255 | N/A | N/A | N/A |
| Category 3 | 104 | 45 | 27 | 26 | 8-43 |
| H: Minor variation | | | | | |
| Category 1 | 4 | 255 | 142 | 143 | 111-172 |
| Category 3 | 1,253 | 45 | 24 | 23 | 1-51 |
| J: Changes to Product Information requiring the evaluation of data | | | | | |
| Category 1 | 63 | 255 | 142 | 140 | 46-228 |

Table 2 Prescription medicine median approval time comparisons

| Application type | Legislated timeframe | Median approval time (TGA working days) | |
|---|---|---|---|
| | | 2015-16 | 2016-17 |
| A: New chemical entity | | | |
| Category 1 | 255 | 199 | 208 |
| B: New fixed-dose combination | | | |
| Category 1 | 255 | 167 | 203 |
| C: Extension of indication | | | |
| Category 1 | 255 | 195 | 202 |
| D: New generic medicine | | | |
| Category 1 | 255 | 158 | 172 |
| E: Additional trade name (ATN)[a] | | | |
| Category 1 | 255 | 219 | 140 |
| ATN | 45 | 35 | 36 |
| F: Major variation | | | |
| Category 1 | 255 | 183 | 185 |
| G: Minor variation[b] | | | |
| Category 1 | 255 | 163 | 0[b] |
| Category 3 | 45 | 19 | 26 |
| H: Minor variation[c] | | | |
| Category 1 | 255 | 146 | 143 |
| Category 3 | 45 | 20 | 23 |
| J: Changes to Product Information requiring the evaluation of data | | | |
| Category 1 | 255 | 134 | 140 |

[a] In July 2015, a legislated 45 working day process for ATN submissions commenced. These applications were under both the Category 1 framework with a legislated timeframe of 255 working days and the new ATN submission framework with a legislated timeframe of 45 working days.

[b] The type G minor variations differ from type H minor variations in that they result in a new ARTG entry. No type G Category 1 applications were approved in 2016-17.

[c] The minor variations (type H) refer to applications to change the formulation, composition or design specification or the container for the goods or any other attribute that results in the goods being separate and distinct. These applications are typically 'Category 3' changes, unless the supporting scientific package contains non-clinical or clinical data in which case the application is a 'Category 1' application.

Figure 1 Submissions received 2015-16 to 2016-17

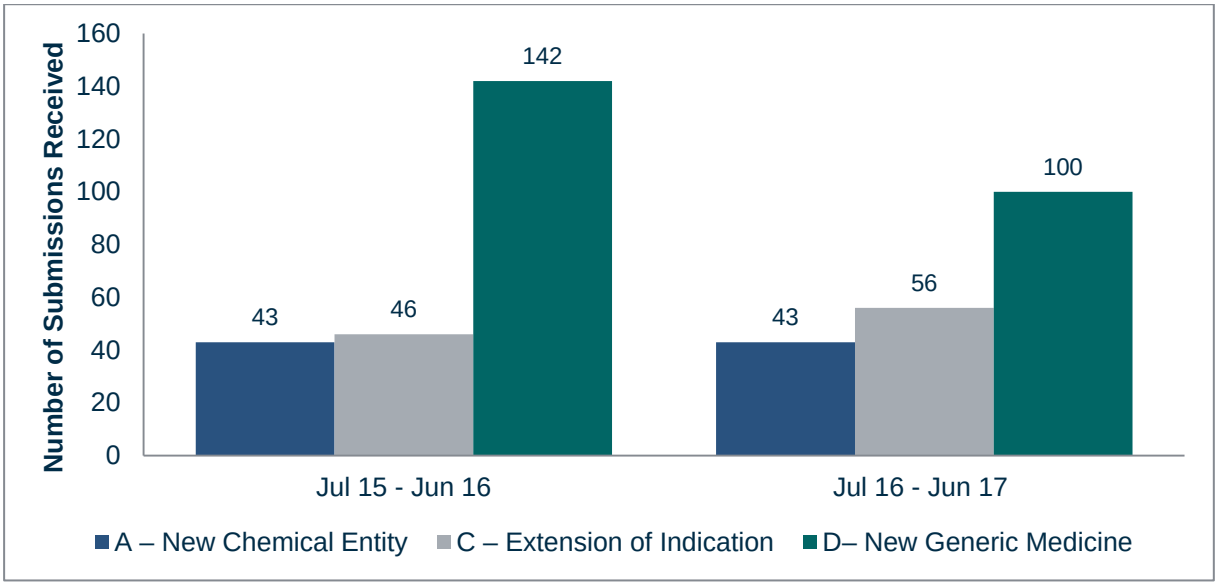



Figure 2 Mean approval times 2015-16 to 2016-17

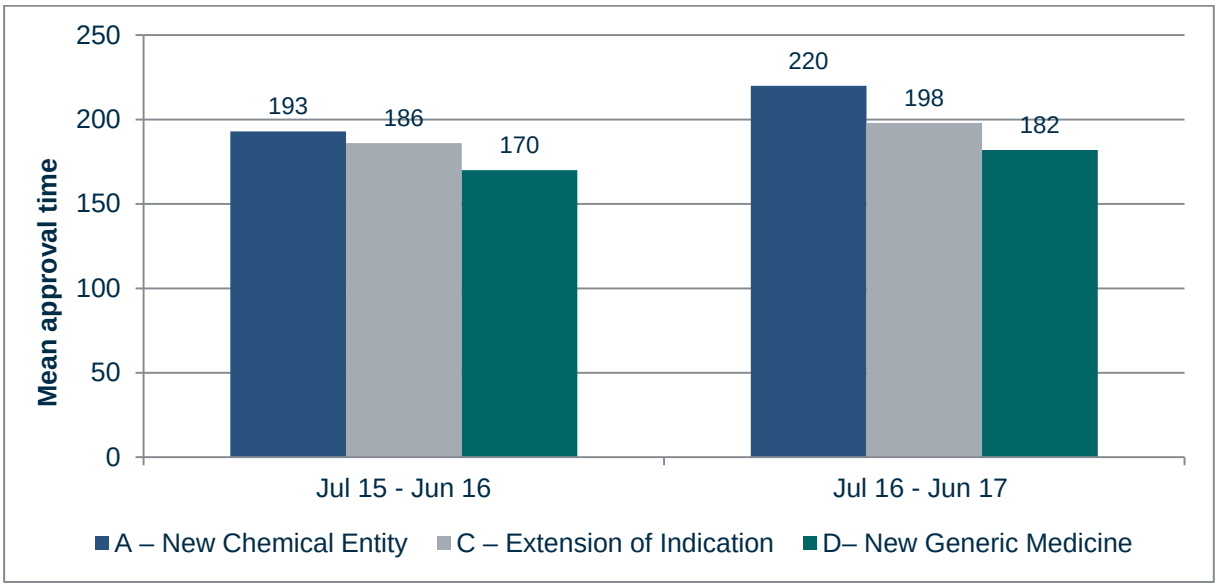
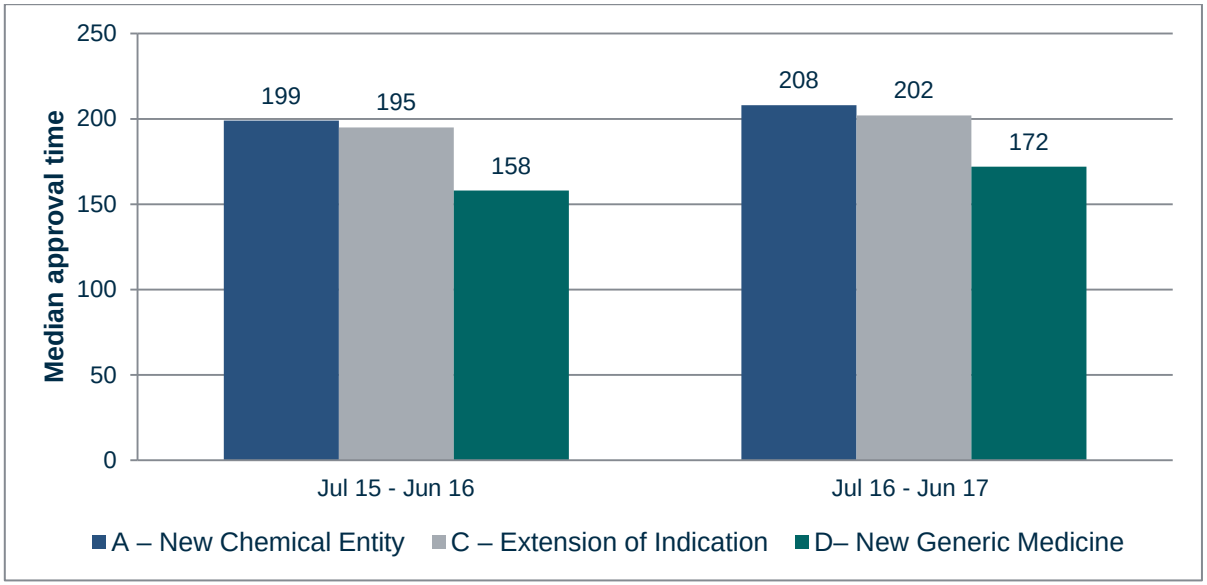


Figure 3 Median approval times 2015-16 to 2016-17




## 1.2. Submission outcomes

Table 3 Number of completed prescription medicine submissions by type and outcome for July 2016 to June 2017

| Submission Type | Approved | Withdrawn | Rejected | Total |
|---|---|---|---|---|
| A: New chemical entity | 38 | 4 | 0 | 42 |
| B: New fixed-dose combination | 4 | 2 | 0 | 6 |
| C: Extension of indication | 45 | 2 | 2 | 49 |
| D: New generic medicine | 111 | 2 | 2 | 115 |
| E: Additional trade name (ATN) (Category 1) | 2 | 0 | 0 | 2 |
| E: ATN | 47 | 1 | 0 | 48 |
| F: Major variation | 46 | 2 | 1 | 49 |
| G: Minor variation | 104 | 2 | 0 | 106 |
| H: Minor variation (Category 1) | 4 | 0 | 0 | 4 |
| H: Minor variation (Category 3) | 1,253 | 16 | 0 | 1,269 |
| J: Changes to Product Information | 63 | 3 | 0 | 66 |
| Total | 1,717 | 34 | 5 | 1,756 |

## 1.3. Other applications

In addition to the application types discussed above, we also process 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 these applications is presented below.

In accordance with the legislation, registered medicines must comply with numerous standards at the time they are registered and throughout their lifecycle. Following an appropriate application and review of the scientific data and safety considerations, we may grant an 'exemption' from a particular standard for a product. The number of applications approved and rejected is also presented below.

Table 4 Number of other prescription medicine applications

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Prescription medicine applications** | | |
| Safety related request | 781 | 738 |
| Self-assessable request | 1,404 | 1,244 |
| Minor editorial change to product information | 481 | 459 |
| Correction of error | 123 | 124 |
| Total | 2,789 | 2,565 |
| **Exemptions to comply with a standard** | | |
| Approved | 88 | 89 |
| Rejected | 0 | 1 |
| Total | 88 | 90 |

## 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 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 5 Number of orphan drug designations

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| Number of designations | 22 | 29 |

# 2. Over-the-Counter medicines

Over-the-Counter (OTC) medicine applications are categorised as new medicine (N) or change (C) applications and are further categorised by risk (N1 and C1 are 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 6 Categorisation of OTC medicine applications

| Application category | Definition |
|---|---|
| N1 | An application submitted as a 'Clone'. |
| N2 | An application which complies with an OTC medicine monograph. |
| N3 | New application for a 'generic' medicine other than those 'generic' applications in levels N1, N2 or N4. |
| N4 | An application for a 'generic' medicine where the medicine:<br>requires supporting safety and/or efficacy (clinical/toxicological) data or a justification for not providing such data; and/or<br>requires a higher level of assessment due to the umbrella branding segment of the product name; and/or<br>has not been previously registered as an OTC medicine following down-scheduling. |
| N5 | An application for a new product that is an extension to a 'generic category' product or an application for a product containing a new chemical entity as an active ingredient. |
| C1 | Quality and non-quality changes classified as 'negligible risk'. |
| C2 | Quality and non-quality changes classified as 'low risk' – no safety and/or efficacy data required; quality data may be required. |
| C3 | Quality and non-quality changes classified as 'low risk' – safety and/or efficacy data required unless justified; quality data may be required.<br>Umbrella branding segment of new name requires a higher level of assessment. |
| C4 | Non-quality changes classified as 'moderate risk' – safety and/or efficacy data required unless justified. |
| B1 | Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that does not contain clinical data. |
| B3 | Request for advice in relation to a registered OTC medicine for the purpose of listing the medicine as a pharmaceutical benefit that contains clinical data or a justification as to why such data is not needed. |
| Requests for consent under section 14/14A of the Act | Request for consent by the Secretary under sections 14 and 14A of the Act to the import, export or supply of therapeutic goods that do not comply with an applicable standard. |

## 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 we were 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 7 Median approval time for OTC medicine applications

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| New medicine applications (days) | | |
| N1 | 14 | 27 |
| N2 | 26 | 43 |
| N3 | 90 | 94 |
| N4 | 89 | 106 |
| N5 | 151 | 192 |
| Change applications (days) | | |
| C1 | 5 | 7 |
| C2 | 8 | 14 |
| C3 | 31 | 14 |
| C4 | 110 | 86 |

Table 8 OTC medicine approval time against target time by application category for July 2016 to June 2017

| Application type | Number completed | Range | Mean | Median | Target time (days) | % within target |
|---|---|---|---|---|---|---|
| New medicines | | | | | | |
| N1 | 93 | 0-41 | 25 | 27 | 45 | 100 |
| N2 | 7 | 37-47 | 42 | 43 | 55 | 100 |
| N3 | 29 | 16-143 | 88 | 94 | 150 | 100 |
| N4 | 29 | 4-162 | 101 | 106 | 170 | 100 |
| N5 | 8 | 45-196 | 167 | 192 | 210 | 100 |
| Change applications | | | | | | |
| C1 | 396 | 0-75 | 8 | 7 | 20 | 97 |
| C2 | 226 | 0-78 | 21 | 14 | 64 | 99.6 |
| C3 | 7 | 10-107 | 30 | 14 | 120 | 100 |
| C4 | 1 | 86 | 86 | 86 | 170 | 100 |

Table 9 Percentage of OTC medicine applications processed within target time

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| New medicine applications (%) | | |
| N1 | 100 | 100 |
| N2 | 100 | 100 |
| N3 | 100 | 100 |
| N4 | 100 | 100 |
| N5 | 83[a] | 100 |
| Change applications (%) | | |
| C1 | 97 | 97 |
| C2 | 99 | 99.6 |
| C3 | 100 | 100 |
| C4 | 100 | 100 |

[a] Of the six N5 applications completed in 2015-16, one was not completed within the target timeframe. This application required referral to the Advisory Committee on Non-prescription Medicines (ACNM), which typically extends the evaluation process by 3-6 months.

## 2.2. Applications

### 2.2.1 New OTC medicine applications

Table 10 Applications received for new OTC medicines and changes to existing medicines

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| New medicine applications | | |
| N1 | 75 | 108 |
| N2 | 13 | 5 |
| N3 | 30 | 44 |
| N4 | 45 | 23 |
| N5 | 14 | 6 |
| Total | 177 | 186 |
| Change applications | | |
| C1 | 632 | 387 |
| C2 | 312 | 276 |
| C3 | 8 | 7 |
| C4 | 1 | 2 |
| Total | 953 | 672 |

### 2.2.2 Completed applications

Table 11 New OTC medicine applications completed and outcomes

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| N1 | | |
| Approved | 79 | 93 |
| Rejected | 0 | 0 |
| Withdrawn by sponsor | 0 | 1 |
| Returned/failed screening | 1 | 0 |
| Total | 80 | 94 |
| N2 | | |
| Approved | 3 | 7 |
| Rejected | 0 | 0 |
| Withdrawn by sponsor | 0 | 1 |
| Returned/failed screening | 5 | 0 |
| Total | 8 | 8 |
| N3 | | |
| Approved | 25 | 29 |
| Rejected | 0 | 0 |
| Withdrawn by sponsor | 7 | 2 |
| Returned/failed screening | 7 | 3 |
| Total | 39 | 34 |
| N4 | | |
| Approved | 50 | 29 |
| Rejected | 0 | 0 |
| Withdrawn by sponsor | 0 | 0 |
| Returned/failed screening | 5 | 6 |
| Total | 55 | 35 |
| N5 | | |
| Approved | 6 | 8 |
| Rejected | 0 | 0 |
| Withdrawn by sponsor | 1 | 0 |
| Returned/failed screening | 5 | 0 |
| Total | 12 | 8 |

Table 12 OTC change applications completed and outcomes

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| C1 | | |
| Approved | 618 | 396 |
| Rejected | 0 | 0 |
| Withdrawn by sponsor | 15 | 10 |
| Returned/failed screening | 0 | 0 |
| Total | 633 | 406 |
| C2 | | |
| Approved | 309 | 226 |
| Rejected | 0 | 0 |
| Withdrawn by sponsor | 3 | 7 |
| Returned/failed screening | 0 | 1 |
| Total | 312 | 234 |
| C3 | | |
| Approved | 4 | 7 |
| Rejected | 0 | 0 |
| Withdrawn by sponsor | 0 | 1 |
| Returned/failed screening | 0 | 2 |
| Total | 4 | 10 |
| C4 | | |
| Approved | 12 | 1 |
| Rejected | 0 | 0 |
| Withdrawn by sponsor | 0 | 0 |
| Returned/failed screening | 0 | 0 |
| Total | 12 | 1 |

### 2.2.3 Other applications

In addition to the application types discussed above, we also process other application types. This includes requests for advice for the purpose of listing a medicine as a pharmaceutical benefit. The number of requests 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, we may grant an 'exemption from a particular standard for a product. The number of applications approved and rejected is also presented below.

Table 13 Number of other OTC medicine applications

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Requests for advice for the purpose of listing a medicine as a pharmaceutical benefit[a]** | | |
| B1 | N/A | 1 |
| B3 | N/A | 1 |
| Total | N/A | 2 |
| **Requests for consent under section 14/14A of the Act to import, export or supply therapeutic goods not complying with an applicable standard[b]** | | |
| Approved | N/A | 25 |
| Rejected | N/A | 1 |
| Total | N/A | 26 |

[a] B1 and B3 requests have recently been implemented. This is the first year for reporting on these application types. Both B1 and B3 applications were approved.

[b] Reporting of requests under section 14/14A of the Act has been introduced in this reporting period.

# 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 us for quality, safety and efficacy prior to being accepted on the ARTG.

Table 14 Registered complementary medicine applications by outcome

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| New medicines | | |
| Approved | 2 | 6 |
| Rejected | 0 | 1 |
| Withdrawn | 1 | 3 |
| Returned/failed screening | 0 | 0 |
| Total new applications completed | 3 | 10 |
| Variations | | |
| Approved | 27 | 20 |
| Rejected | 0 | 1 |
| Withdrawn | 3 | 3 |
| Returned/failed screening | 0 | 0 |
| Total variations completed | 30 | 24 |
| Application for consent to import, supply or export goods under section 14/14A of the Act[a] | | |
| Approved | 1 | 1 |
| Rejected | 0 | 0 |
| Total applications completed | 1 | 1 |

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

## 3.2. New ingredients permitted for use in listed medicines

Table 15 New listed medicine ingredient applications by outcome

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Application outcome** | | |
| Approved | 18[a] | 79[b] |
| Rejected | 0 | 0 |
| Withdrawn | 0 | 1 |
| Returned/failed screening | 2 | 0 |
| Total completed | 20 | 80 |

[a] This includes 10 ingredients that were permitted as per the Therapeutic Goods (Listing) Notice 2015 (No. 4) following TGA initiated assessments.

[b] This includes a large number of ingredients that were made available for excipient use in specific circumstances in listed medicines following TGA initiated assessments.

## 3.3. Listed medicines

Table 16 New listed medicines

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| New listed medicines | 1,644 | 1,581 |

Table 17 Listed medicine variations under section 9D of the *Therapeutic Goods Act 1989*

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Medicine variation** | | |
| Approved | 102 | 85 |
| Rejected | 16 | 4 |
| Total | 118 | 89 |

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

Table 18 Listed medicine applications under section 14/14A of *the Therapeutic Goods Act 1989*

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Application** | | |
| Exemption[a] granted | 7 | 7 |
| Rejected | 4 | 2 |
| Total | 11 | 9 |

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

### 3.3.1 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 19 Listed medicine investigations undertaken and outcomes

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| Initiated investigations | 114 | 201 |
| **Completed investigations** | | |
| Medicines prioritised for targeted review | 69 | 134 |
| Referred to another TGA area or government organisation | 14 | 18 |
| No further action taken[a] | 32 | 54 |
| Total completed investigations | 115 | 206 |

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

### 3.3.2 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 against selected listing requirements, the review is concluded and the medicine remains on the ARTG
- compliance breaches are identified for the selected listing requirements
- the review is not completed as the sponsor has cancelled the medicine
- the review is closed due to the unavailability of information in determining its compliance status.

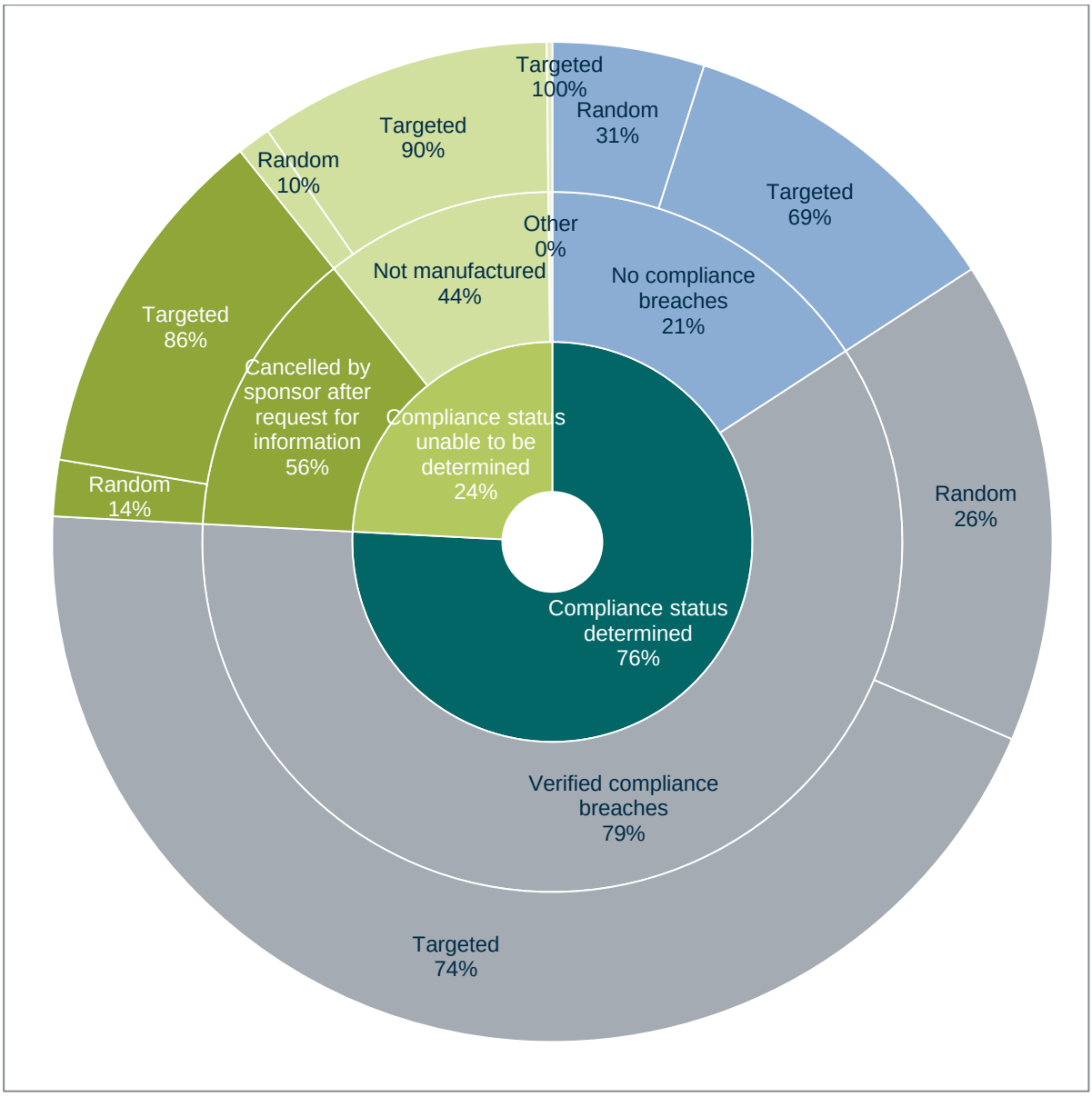
Table 20 Listed medicine reviews by type

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Initiated reviews** | | |
| Targeted reviews | 173 | 504 |
| Random reviews | 340 | 87 |
| Total | 513 | 591 |
| Reviews on hand | 151 | 189 |
| **Completed reviews** | | |
| Targeted reviews | 158 | 421 |
| Random reviews | 315 | 130 |
| Total | 473 | 551 |

Table 21 Completed listed medicine reviews by outcome

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Compliance status determined** | | |
| Medicines with no compliance breaches | 81 | 87 |
| Medicines with verified compliance breaches | 327 | 330 |
| Sub-total | 408 | 417 |
| **Compliance status unable to be determined** | | |
| Medicines cancelled by sponsors after request for information | 43 | 74 |
| Medicines not yet manufactured | 19 | 58 |
| Other | 1 | 1 |
| Sub-total | 63 | 133 |
| **Product not a therapeutic good** | 2 | 1 |
| Total completed | 473 | 551 |

Figure 4 Outcomes of compliance reviews by reason for initiation




In this period, we have performed a higher proportion of targeted reviews than in 2015-16. We initiated a number of targeted compliance projects based on the compliance data obtained from the previous reporting period. These projects have covered oral probiotics indicated for vaginal conditions and listed medicines with blood glucose and cholesterol indications. Of the reviews where we were able to determine a compliance status, 79% had verified compliance breaches, which is consistent with the non-compliance rate from the previous period, despite the different proportion of random to targeted reviews.

Table 22 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.

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Type of compliance issue** | | |
| Information provided in ARTG entry | 53 | 119 |
| Manufacturing, quality and/or formulation | 63 | 62 |
| Labelling[a] | 110 | 94 |
| Advertising[a] | 71 | 86 |
| Unacceptable presentation[a] | 119 | 140 |
| Evidence[b] | 210 | 180 |
| Safety[c] | 13 | 22 |
| Non-response to a request for information[d] | 6 | 8 |
| Other[d] | 2 | 4 |

[a] In previous reports 'Labelling', 'Advertising' and 'Unacceptable presentation' were reported collectively as 'Labelling and/or advertising'. The 2015-16 data has been updated to incorporate the additional breakdown of categories. 'Unacceptable presentation' includes the presentation (labelling, packaging and any advertising material) being misleading to consumers and text and graphics being unacceptable.

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

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

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

## Figure 5 Types of compliance issues identified by reason for initiation

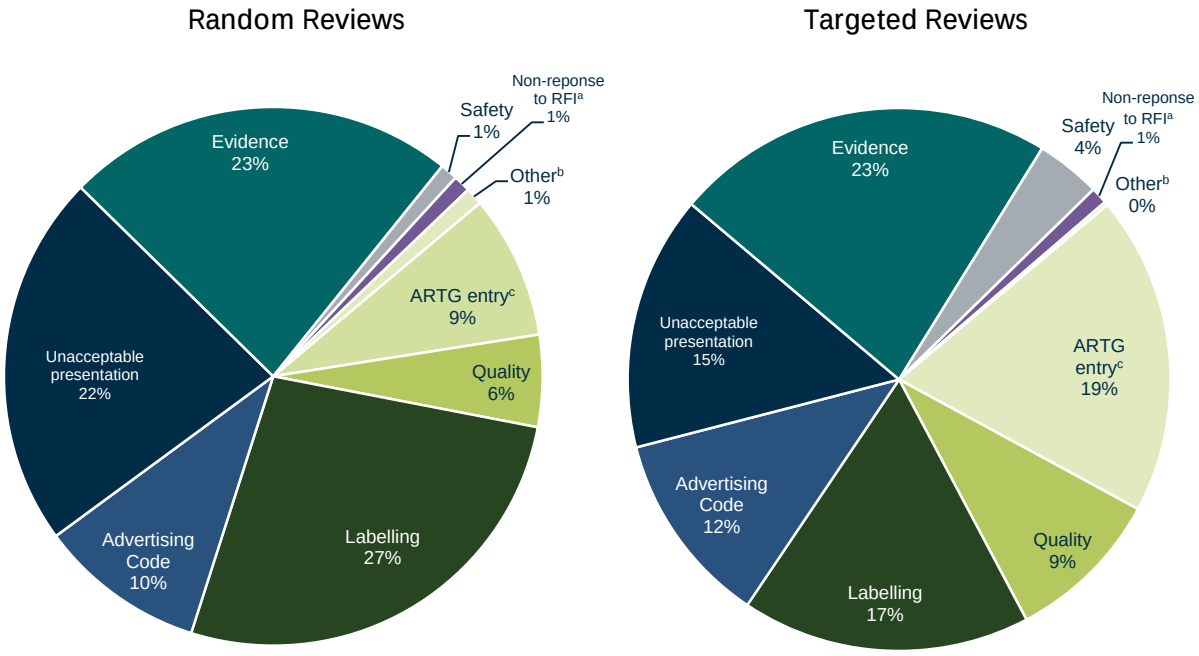



Figure 5 shows the types of compliance issues that are identified through reviews which are either randomly selected or targeted for a particular issue. Multiple breaches may be identified for each medicine that is found to be non-compliant; for example, 54% of non-compliant medicines were found to have insufficient evidence to support the medicine indication, yet this breach accounted for 23% of the total breaches identified across all non-compliant medicines.

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

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

[c] 'ARTG entry' broadly refers to situations where the information on the ARTG is incorrect, including indications that are not eligible for listing and ingredients that do not comply with listing requirements.

For both random and targeted reviews, the most common compliance issues have consistently been labelling/ advertising and evidence issues. For targeted reviews in 2016-17, there was a slightly higher proportion of compliance issues related to the ARTG, quality or safety, whereas in 2015-16 there was a significantly higher proportion of evidence and labelling/advertising issues. This is likely to be the result of a number of targeted compliance projects undertaken during this period that focussed on these issues.

Table 23 Actions taken following listed medicine reviews

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Actions following a Request for Information** | | |
| Medicines found to be compliant and review concluded | 81 | 87 |
| Medicines cancelled by the TGA without a proposal to cancel notice | 0 | 0 |
| Proposal to cancel notice or warning[a] sent by the TGA | 327 | 330 |
| Total | 408 | 417 |
| **Actions following Proposal to Cancel notice[b]** | | |
| Medicines cancelled by the TGA | 44 | 17 |
| Medicines cancelled by sponsors after being notified of compliance breaches | 76 | 84 |
| Reviews concluded after compliance breaches were addressed | 207 | 229 |

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

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

Figure 6 Outcomes of completed compliance reviews

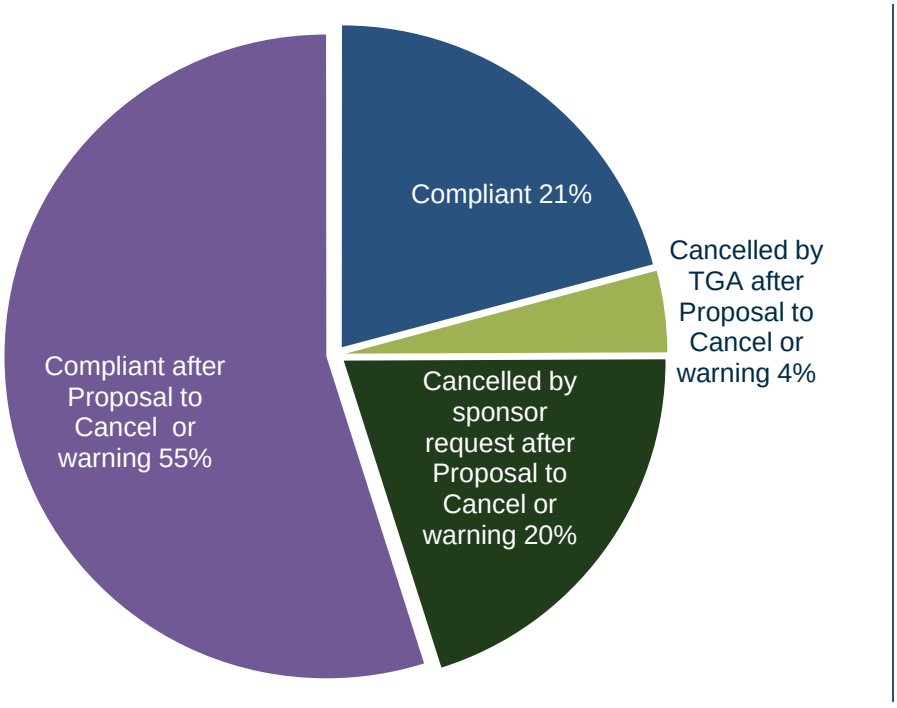



Figure 6 shows that a significant proportion of listed medicine reviews are concluded after the sponsor has adequately addressed the compliance breaches identified by us. Under the *Therapeutic Goods Act 1989* sponsors are given an opportunity to respond to issues raised during a compliance review. There was a slight decrease in the number of listed medicines cancelled by the TGA following a Proposal to cancel or warning letter (4%) compared with the previous period (11%). The high proportion of listed medicines that are brought back into compliance after a Proposal to cancel, combined with the decrease in listed medicines cancelled by the TGA, shows that industry is willing to work with us to ensure the supply of listed medicines on the ARTG is compliant.

# 4. Biologicals

The *Australian Regulatory Guidelines for Biologicals* define the different biological classes.

## 4.1. Inclusion of biologicals

Table 24 Applications for biologicals received and on hand

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Applications received** | | |
| Technical Master File (TMF)[a] new | 2 | 0 |
| TMF annual updates | 6 | 5 |
| TMF variations | 9 | 20 |
| TMF notifications | 7 | 27 |
| Plasma Master File[b] annual updates | 15 | 11 |
| Biological Class 2 – new applications | 2 | 4 |
| Biological Class 3 – new applications | 2 | 0 |
| Biological Class 2 – variations | 26 | 14 |
| Biological Class 3 – variations | 2 | 1 |
| Total received | 71 | 82 |
| **Applications on hand** | | |
| TMF new | 2 | 1 |
| TMF annual updates | 4 | 4 |
| TMF variations | 2 | 7 |
| TMF notifications | 0 | 0 |
| Plasma Master File annual updates | 3 | 4 |
| Biological Class 2 – new applications | 3 | 6 |
| Biological Class 3 – new applications | 4 | 3 |
| Biological Class 2 – variations | 7 | 2 |
| Biological Class 3 – variations | 1 | 0 |
| Total on hand | 26 | 27 |

[a] Technical Master Files (TMF) contain information from manufacturers that demonstrate how product safety and quality standards have been met for Blood, Blood Components and Haematopoietic Progenitor Cells.

[b] Plasma Master Files contain control strategies that ensure the quality and safety of plasma, from collection through to plasma pooling prior to fractionation and including donor selection criteria and testing, which are part of medicinal products or medical devices.

Table 25 Completed applications for biologicals

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Biologicals applications** | | |
| Technical Master File (TMF) new | 2 | 1 |
| TMF annual updates | 5 | 5 |
| TMF variations | 7 | 19 |
| TMF notifications | 7 | 27 |
| Plasma Master File annual updates | 14 | 7 |
| Biological Class 2 – new applications | 4 | 1 |
| Biological Class 3 – new applications | 0 | 1 |
| Biological Class 2 – variations | 21 | 18 |
| Biological Class 3 – variations | 5 | 2 |
| Total completed | 65 | 81 |

# 5. Medicine and vaccine adverse event reports

## 5.1. Adverse medicine and vaccine reaction notifications

Table 26 Source of notifications of medicine and vaccine adverse reactions

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Reports with clear causality by reporter** | | |
| Hospitals | 2,194 | 1,850 |
| Companies | 8,776 | 9,194 |
| General practitioners | 644 | 573 |
| Specialists | 221 | 245 |
| Pharmacists | 883 | 1,063 |
| Members of the public | 813 | 1,104 |
| Nurses, dentists, complementary healthcare practitioners | 214 | 157 |
| State/Territory Health departments | 2,619 | 3,274 |
| **Reports withdrawn, or rejected, or without clear causality** | | |
| | 1,269 | 2,276 |
| Total received | 17,633 | 19,736 |
| Mean number of reports received weekly | 339 | 380 |
| Vaccine reports included in this table | 3,361 | 4,020 |

# 6. Medical Devices

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

- **Conformity assessment:** Is the systematic examination by the manufacturer to determine that a medical device is safe and performs as intended and, therefore, conforms to the Essential Principles. Certification of the manufacturer's conformity assessment procedure may (and in some cases must) be undertaken by the TGA, or we may recognise conformity assessment certification from European notified bodies.
- **Inclusion on the ARTG:** Medical devices cannot be imported, supplied in, or exported from Australia unless they are included on the ARTG or a valid exemption applies, for example custom made medical devices, importation of samples, etc. A sponsor can apply to include a medical device on the ARTG if the device complies with the Essential Principles and appropriate conformity assessment procedures have been applied to the device (typically demonstrated through conformity assessment certification).
- **Post-market monitoring:** Once a medical device has been included on the ARTG the device must continue to meet all the regulatory, safety and performance requirements and standards that were required for the approval.

## 6.1. Conformity assessment

### 6.1.1 Applications

Table 27 Number of conformity assessment applications (medical devices including IVDs)

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Conformity assessment applications** | | |
| Applications received | 257 | 242 |
| Applications on hand | 178 | 213 |
| Applications completed | 187[a] | 204 |

[a] Due to a correction in coding, a small variation has occurred to the data.

### 6.1.2 Outcomes

Table 28 Outcomes of conformity assessment applications

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **New** | | |
| Approved | 49 | 37 |
| Rejected | 3 | 1 |
| Withdrawn / Lapsed | 23 | 20 |
| **Variation (changes and re-certifications)** | | |
| Approved | 91 | 124 |
| Rejected | 3 | 2 |
| Withdrawn / Lapsed | 18 | 20 |
| Total | 187 | 204 |

Table 30 has been broken down into 'New' and 'Variation' assessment application to provide additional transparency and understanding. In reviewing the changes in reporting the final total was increased by one, as per updates to operational data.

### 6.1.3 Processing times

We are 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 we were unable to progress the application until the sponsor provided additional information unless otherwise specified.

Table 29 TGA processing times for new devices and variations

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **New devices** | | |
| Mean TGA processing time (days) | 133 | 129 |
| Median TGA processing time (days) | 178 | 167 |
| **Variations (changes and recertifications)** | | |
| Mean TGA processing time (days) | 93 | 114 |
| Median TGA processing time (days) | 71 | 101 |

During 2016-17, 100% of conformity assessment applications were completed within 200 working days.

## 6.2. Inclusion of medical devices (including IVDs)

### 6.2.1 Applications

Table 30 Applications for inclusion – medical devices (including IVDs)

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| Class I medical devices[a] | | |
| Applications received | 2,685 | 2,514 |
| Applications completed | 2,690 | 2,431 |
| Class I measuring medical devices | | |
| Applications received | 48 | 51 |
| Applications completed | 48 | 50 |
| Applications on hand[b] | 2 | 4 |
| Class I sterile medical devices | | |
| Applications received | 257 | 246 |
| Applications completed | 253 | 255 |
| Applications on hand[b] | 11 | 3 |
| Class IIa medical devices | | |
| Applications received | 1,178 | 1,160 |
| Applications completed | 1,206 | 1,178 |
| Applications on hand[b] | 58 | 51 |
| Class IIb medical devices | | |
| Applications received | 654 | 666 |
| Applications completed | 716 | 682 |
| Applications on hand[b] | 40 | 34 |
| Class III medical devices | | |
| Applications received | 344 | 343 |
| Applications completed | 249 | 471 |
| Applications on hand[b] | 313 | 180 |
| Class III Joint Reclassification medical devices[c] | | |
| Applications received | 0 | 0 |
| Applications completed | 355 | 203 |
| Applications on hand[b] | 294 | 94 |

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Active Implantable Medical Devices (AIMD)** | | |
| Applications received | 49 | 48 |
| Applications completed | 19 | 87 |
| Applications on hand[b] | 62 | 23 |
| **Class 1 IVDs[d]** | | |
| Applications received | 92 | 94 |
| Applications completed | 112 | 91 |
| Applications on hand[b] | 1 | 4 |
| **Class 2 IVDs** | | |
| Applications received | 104 | 96 |
| Applications completed | 148 | 94 |
| Applications on hand[b] | 10 | 12 |
| **Class 3 IVDs** | | |
| Applications received | 65 | 49 |
| Applications completed | 131 | 45 |
| Applications on hand[b] | 11 | 15 |
| **Class 4 IVDs** | | |
| Applications received | 25 | 15 |
| Applications completed | 29 | 15 |
| Applications on hand[b] | 0 | 0 |

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

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

[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.

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

### 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 31 Outcomes of medical device applications by classification

| | Number of applications | | | | | |
|---|---|---|---|---|---|---|
| | 2015-16 | | | 2016-17 | | |
| Device Classification | Approved/ Accepted | Rejected/ Lapsed | Withdrawn | Approved/ Accepted | Rejected/ Lapsed | Withdrawn |
| Class I | 2,690 | 0 | 0 | 2,431 | 0 | 0 |
| Class I Measurement | 47 | 0 | 1 | 44 | 2 | 4 |
| Class I Sterile | 234 | 0 | 19 | 248 | 0 | 7 |
| Class IIa | 1,132 | 2 | 72 | 1,128 | 6 | 44 |
| Class IIb | 679 | 1 | 36 | 659 | 3 | 20 |
| Class III | 207 | 12 | 30 | 398 | 18 | 55 |
| Class III Reclassification | 278 | 7 | 70 | 152 | 3 | 48 |
| AIMD | 17 | 0 | 2 | 87 | 0 | 0 |
| Class 1 IVD[a] | 112 | 0 | 0 | 84 | 0 | 7 |
| Class 2 IVD[a] | 136 | 3 | 9 | 71 | 2 | 21 |
| Class 3 IVD[a] | 123 | 1 | 7 | 37 | 0 | 8 |
| Class 4 IVD[a] | 28 | 0 | 1 | 14 | 0 | 1 |

[a] The IVD transition period ended on 30 June 2015, with a number of applications received late in the transition period. The higher number of applications completed in 2015-16 reflected the end of this transition period.

### 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 we are waiting for information or payment of fees (reflected in 'sponsor days').

Table 32 Processing times for medical device application audits (including IVDs)

| | 2015-16 | | | 2016-17 | | |
|---|---|---|---|---|---|---|
| | Number of applications | Sponsor days | TGA days[a] | Number of applications | Sponsor days | TGA days[a] |
| **Mean Processing Time** | | | | | | |
| Medical devices | | | | | | |
| Applications completed without audit | 2,112[b] | | | 2,105 | | |
| Non-compulsory audit[c] | 497 | 30 | 43 | 310 | 42 | 55 |
| Level 1 compulsory audit | 32 | 27 | 26 | 40 | 25 | 18 |
| Level 2 compulsory audit | 205 | 55 | 161 | 471 | 74 | 159 |
| IVDs | | | | | | |
| Applications completed without audit | 148[b] | | | 77 | | |
| IVD non-compulsory audit | 17 | 41 | 65 | 10 | 35 | 46 |
| IVD compulsory audit | 159 | 26 | 45 | 82 | 29 | 39 |
| **Median Processing Time** | | | | | | |
| Medical devices | | | | | | |
| Applications completed without audit | 2,112[b] | | | 2,105 | | |
| Non-compulsory audit[c] | 497 | 21 | 21 | 310 | 27 | 24 |
| Level 1 compulsory audit | 32 | 23 | 9 | 40 | 23 | 13 |
| Level 2 compulsory audit | 205 | 49 | 158 | 471 | 60 | 155 |
| IVDs | | | | | | |
| Applications completed without audit | 148[b] | | | 77 | | |
| IVD non-compulsory audit | 17 | 33 | 58 | 10 | 22 | 36 |
| IVD compulsory audit | 159 | 21 | 41 | 82 | 18 | 29 |

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

[b] Auto-included applications for Class I and Class 1 IVD are complete within 24 hours, and not included in the figures above.

[c] Non-compulsory audit – estimate for the audit processing time does not include applications for reclassification of joint replacement medical devices received during transitional period (Class III Joint Reclassification medical devices), and applications supported by European Community (EC) certificates issued by certain notified bodies.

## 6.3. Post-market monitoring

### 6.3.1 Compliance reviews

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

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

Table 33 Restricted word Class 1 medical device and targeted compliance reviews

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Restricted word reviews** | | |
| Reviews completed | 0 | 54 |
| Reviews commenced | 1 | 55 |
| Reviews on hand | 1 | 1 |
| **Targeted compliance reviews[a]** | | |
| Reviews completed | 104 | 35 |
| Reviews commenced | 83 | 45 |
| Reviews on hand | 164 | 175 |

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

### 6.3.2 Post-market reviews

We also undertake a range of post market reviews.

Table 34 Medical device targeted reviews

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Post market reviews** | | |
| Reviews commenced – number of ARTG entries | 80 | 396 |
| Reviews completed – number of ARTG entries | 83 | 239 |
| Reviews on hand – number of ARTG entries | 163 | 263 |

### 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 35 Number of medical device incident reports and processing times

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Device incident reports** | | |
| Reports received | 3,841 | 4,896 |
| Reports completed | 3,608 | 4,918 |
| Reports still in progress | 207 | 380 |
| **Processing time** | | |
| Mean TGA processing time (days) | 1 | 1 |
| Median TGA processing time (days) | 14 | 10 |
| Percentage processed within target timeframe | 100% | 95% |

Table 36 Medical device incident report outcomes[a]

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Incident report outcome** | | |
| Reviewed and used for trend analysis purposes | 2,988 | 4,125 |
| Reviewed, no further action required | 330 | 279 |
| Product recall | 40 | 70 |
| Recall for product correction | 19 | 4 |
| Hazard alert | 25 | 22 |
| Product notification | 1 | 0 |
| Safety alert | 9 | 20 |
| Product enhancement/improvement notice | 0 | 1 |
| Instructions for use amended | 3 | 5 |
| Referral for post-market review | 23 | 82 |
| Refer to another TGA Branch | 51 | 39 |
| Company warned | 0 | 13 |
| Product suspended from ARTG | 0 | 0 |
| Product cancelled from ARTG | 4 | 1 |
| Manufacturing process improvements | 10 | 12 |
| Quality system process improvements | 1 | 0 |
| Maintenance carried out by the hospital | 0 | 0 |
| Change to design | 13 | 3 |
| Not device related | 9 | 16 |
| Other | 39 | 81 |

[a] Outcomes are not mutually exclusive.

### 6.3.4 Devices manufacturing

Table 37 Outcomes of Quality Management System (QMS) audits of Australian manufacturers

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **QMS audits (Australia)** | | |
| Number of audits conducted | 38 | 38 |
| Satisfactory compliance (of completed audits) | 79% | 71% |
| Marginal compliance (of completed audits) | 21% | 24% |
| Unacceptable (of completed audits) | 0% | 0% |
| Close-out in Progress | 0% | 5% |
| **Processing time** | | |
| Initial audits conducted within 3 months of application[a] | 17% | 57% |
| Re-audits conducted within 6 months of due date | 41% | 16% |

a The improvement in processing times for initial audits was the outcome of process improvement resulting in more timely internal notification of required audits, and more up to date status of manufacturers due to the Medical Devices Single Audit Program (MDSAP).

Table 38 Outcomes of QMS audits of overseas manufacturers

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **QMS audits (overseas)** | | |
| Number of audits conducted | 20 | 26 |
| Satisfactory compliance (of completed audits) | 75% | 92% |
| Marginal compliance (of completed audits) | 15% | 0% |
| Unacceptable (of completed audits) | 10% | 0% |
| Close-out in Progress | 0% | 8% |
| **Processing time** | | |
| Initial certification audits conducted within 6 months of application[a] | 50% | 80% |
| Certification re-audits conducted within 6 months of due date | 17% | 9% |

a The improvement in processing times for initial audits was the outcome of process improvement resulting in more timely internal notification of required audits, and more up to date status of manufacturers due to the MDSAP.

# 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 we were 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 39 Approval times for export only medicines

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **New applications** | | |
| Mean TGA processing time (days) | 21 | 25 |
| Median TGA processing time (days) | 20 | 26 |
| Percentage processed within target processing time | 98% | 75% |
| **Variations** | | |
| Mean TGA processing time (days) | 18 | 22 |
| Median TGA processing time (days) | 16 | 22 |
| Percentage processed within target processing time | 100% | 89% |

Table 40 Applications for new and variations to export only medicines

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Export only applications** | | |
| Applications received | 241 | 242 |
| Applications awaiting response from sponsor | 20 | 9 |
| **Applications completed** | | |
| Approved | 221 | 207 |
| Withdrawn | 10 | 17 |
| Total completed | 231 | 224 |

## 7.2. Export certifications for medicines

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

Table 41 Export certification applications and processing times

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| Applications received | 2,124 | 1,582 |
| **Applications completed** | | |
| Approved | 2,127 | 1,413 |
| Withdrawn | 18 | 3 |
| Total completed | 2,145 | 1,416 |
| **Processing times** | | |
| Mean TGA processing time (days) | 12 | 12 |
| Median TGA processing time (days) | 12 | 13 |
| Percentage processed within target time[a] | 98% | 99% |

[a] We aim to have 100% of applications processed within the target timeframe.

## 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.

Table 42 Medical device applications and processing times for export certification assessments

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| Applications received | 496 | 553 |
| **Applications completed** | | |
| Export certificates issued | 483 | 504 |
| Applications withdrawn | 3 | 10 |
| Total completed | 486 | 514 |
| **Processing time** | | |
| Mean TGA processing time (days) | 4 | 4.5 |
| Median TGA processing time (days) | 5 | 4 |
| Percentage processed within target time[a] | 96% | 83% |

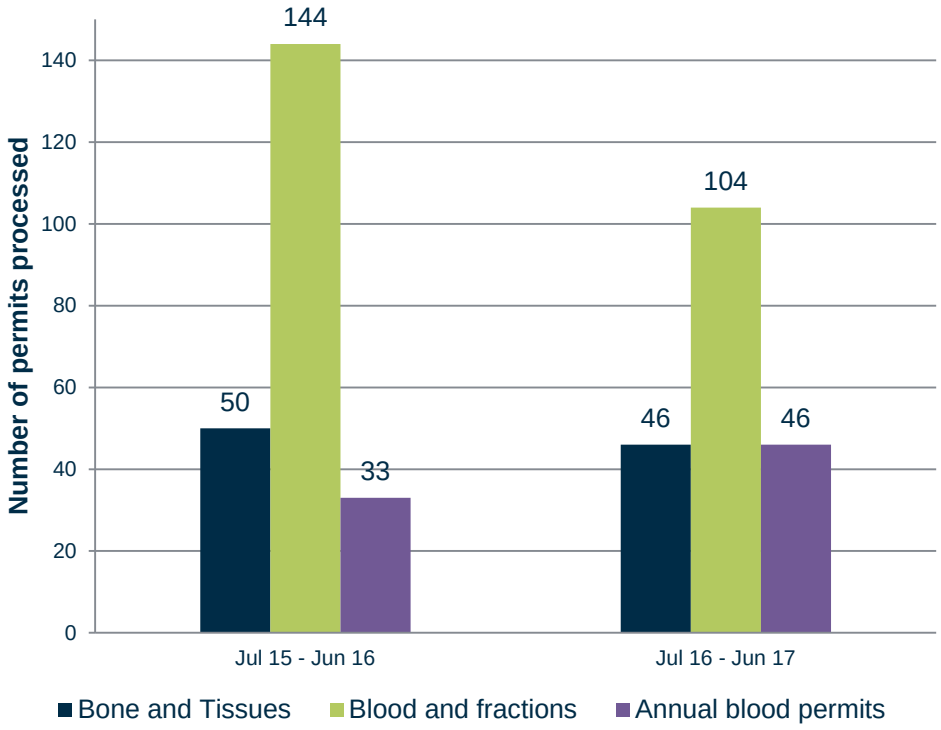
[a] We aim to have at least 90% of applications processed within the target timeframe.

## 7.4. Blood permits for export

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

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

Figure 7 Number of blood permits processed



# 8. Access to unapproved therapeutic goods

## 8.1. Special Access Scheme

The SAS refers to arrangements which provide for the import and/or supply of an unapproved therapeutic good for a single patient, on a case by case basis. For this reporting period, two pathways existed under the scheme and they are categorised as follows:

- Category A is a **notification pathway** which can only be accessed by medical practitioners for patients who are seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment.
- Category B is an **application pathway** which can be accessed by health practitioners for patients that do not fit the Category A definition. An approval letter from TGA is required before the goods may be accessed.

Any unapproved therapeutic good can potentially be supplied via the SAS except for drugs of abuse in Schedule 9 of the Poisons Standard (where the manufacture, possession, sale or use is prohibited by State or Territory law) which cannot be accessed through the SAS Category A process.

Table 43 SAS medicine notifications and applications

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Category A notifications** | | |
| Total Category A notifications | 38,806 | 46,678 |
| **Category B applications** | | |
| Approved | 19,307 | 21,609 |
| Cancelled | 312 | 355 |
| Rejected | 51 | 21 |
| Pending at end of reporting period | 443 | 418 |
| Total Category B applications | 20,113 | 22,403 |

Table 44 SAS device notifications and applications

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Category A notifications** | | |
| Total | 3,922 | 4,914 |
| **Category B applications** | | |
| Approved | 2,081 | 2,113 |
| Cancelled | 116 | 96 |
| Rejected | 20 | 1 |
| Pending at end of reporting period | 16 | 135 |
| Total | 2,233 | 2,345 |

Table 45 SAS biological notifications and applications

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Category A notifications** | | |
| Total | 44 | 47 |
| **Category B applications** | | |
| Approved | 3,171 | 2,024 |
| Cancelled | 25 | 89 |
| Rejected | 0 | 0 |
| Pending at end of reporting period | 35 | 44 |
| Total | 3,231 | 2,157 |

## 8.2. Clinical trials

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

Table 46 Number of notifications for new clinical trials involving unapproved therapeutic goods received by therapeutic good type

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Therapeutic good type** | | |
| Medicine | 458 | 409 |
| Device[a] | 155 | 152 |
| Biological | 21 | 10 |
| Medicine and device | 288 | 290 |
| Device and biological | 6 | 1 |
| Medicine and biological | 14 | 6 |
| Medicine, device and biological | 7 | 0 |
| Total | 949 | 868 |

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

Table 47 Number of new clinical trial notifications involving unapproved therapeutic goods received by phase

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Clinical trial type** | | |
| Phase 1 | 205 | 191 |
| Phase 2 | 217 | 189 |
| Phase 3 | 301 | 257 |
| Phase 4 | 146 | 89 |
| Device[a] | N/A | 118 |
| Bioavailability/equivalence | 39 | 24 |
| None specified[b] | 134 | N/A |

[a] In previous reports 'Device' was not available as a phase category under the previous CTN system.

[b] It is now always possible to specify phase and the 'None specified' category will no longer be used.

Table 48 Number of notifications for new clinical trials and variations to previously notified clinical trials, including non-fee attracting variations, involving unapproved therapeutic goods received by therapeutic good type

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Therapeutic good type** | | |
| Medicine | 1,090 | 1,230 |
| Device[a] | 249 | 266 |
| Biological | 31 | 12 |
| Medicine and device | 1,072 | 1,417 |
| Device and biological | 20 | 2 |
| Medicine and biological | 37 | 10 |
| Medicine, device and biological | 27 | 1 |
| Total | 2,526 | 2,938 |

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

The online system captures the actual number of notifications received for new clinical trials and requests to change significant details to clinical trials already notified. A variation to a previously notified clinical trial may include an addition of a site(s), change to a therapeutic good, or change in principal investigator etc

Table 49 Number of new clinical trials and variations[a] to previously notified clinical trials involving unapproved therapeutic goods received by phase

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Phases** | | |
| Phase 1 | 415 | 459 |
| Phase 2 | 598 | 648 |
| Phase 3 | 1,177 | 1,358 |
| Phase 4 | 274 | 246 |
| Device[b] | N/A | 194 |
| Bioavailability/equivalence | 46 | 33 |
| None specified[c] | 217 | N/A |

[a] A variation may include any change to a previously notified clinical trial such as an additional site, change to a therapeutic good, or change in principal investigator.

[b] In previous reports 'Device' was not available as a phase category under the previous CTN system.

[c] It is now always possible to specify phase and the 'None specified' category will no longer be used.

## 8.3. Authorised Prescribers

The Authorised Prescriber Scheme allows approved medical practitioners authority to prescribe a specified unapproved therapeutic good(s) to patients who are identified by their medical condition. If a medical practitioner becomes an Authorised Prescriber they may prescribe the product to patients in their immediate care, within the indication specified, without seeking further approval from the TGA.

Table 50 Authorised Prescriber approvals for medicines, medical devices and biologicals

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Approvals by therapeutic good type** | | |
| Number of approvals for medicines | 661 | 764 |
| Number of approvals for medical devices | 238 | 304 |
| Number of approvals for biologicals | 0 | 1 |

# 9. Medicines and biologicals manufacturing

## 9.1. Manufacturing licences issued to Australian manufacturers

Table 51 Status of manufacturing licence applications

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Licence status (Australia)** | | |
| New licences granted | 15 | 9 |
| Withdrawn application | 11 | 10 |
| Revoked licences – at request of licence holder | 42 | 19 |
| Revoked licences – TGA | 0 | 1 |
| Suspended – at request of licence holder | 3 | 1 |
| Suspended – TGA | 0 | 0 |

As at 30 June 2017, there were 247 Australian companies holding manufacturing licences covering 387 sites.

Table 52 Outcomes of inspections of Australian manufacturers

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Inspection status (Australia)** | | |
| Number of inspections conducted | 220 | 185 |
| Satisfactory compliance (of completed inspections) | 81% | 88% |
| Marginal compliance (of completed inspections) | 18% | 10% |
| Unacceptable (of completed inspections) | 1% | 2% |
| Close-out in progress | 15% | 18% |
| **Processing time** | | |
| Initial inspections conducted within 3 months of application | 68% | 85% |
| Re-inspections conducted within 6 months of due date | 54% | 61% |

The 2016-17 data excludes inspections conducted for Australian medical devices manufacturers. This information is now reported under medical devices as Quality Management System (QMS) audits of Australian manufacturers.

The number of initial inspections conducted within 3 months of application improved in 2016-17 due to improved internal processes and focused efforts on ensuring initial inspections were conducted in a timely manner.

## 9.2. Approval (certification) of overseas manufacturers

Table 53 Manufacturing certification application by status (overseas)

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Applications (overseas)** | | |
| New applications received | 38 | 46 |
| Re-inspection applications | 52 | 38 |
| **Applications completed** | | |
| Certified | 44 | 33 |
| Rejected | 28 | 59 |
| Total completed | 72 | 92 |

As at 30 June 2017, there were 206 overseas manufacturers covering 207 manufacturing sites that were subject to TGA inspection and approximately 2,700 overseas manufacturing sites that relied on evidence from recognised regulators.

Table 54 Outcomes of inspections of overseas manufacturers

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Inspection status (overseas)** | | |
| Number of inspections conducted | 76 | 58 |
| Satisfactory compliance (of completed inspections) | 95% | 94% |
| Marginal compliance (of completed inspections) | 4% | 6% |
| Unacceptable (of completed inspections) | 1% | 0% |
| Close-out in progress | 18% | 10% |
| **Processing time** | | |
| Initial certification inspections conducted within 6 months of application | 40% | 64% |
| Certification re-inspections conducted within 6 months of due date | 75% | 66% |

The 2016-17 data excludes inspections conducted for overseas medical devices manufacturers. This information is now reported under medical devices as QMS audits of overseas manufacturers.

The number of initial overseas inspections conducted within six months of application improved in 2016-17 due to improved internal processes and focused efforts on ensuring initial inspections were conducted in a timely manner.

## 9.3. Good Manufacturing Practice clearances

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

Table 55 GMP clearance application status

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| Applications received | 5,657 | 6,506 |
| **Applications completed** | | |
| Approved | 5,132 | 5,067 |
| Rejected | 263 | 642 |
| Total completed | 5,395 | 5,709 |

# 10. Recalls

## 10.1. Medicine recalls

Table 56 Medicine recalls by reason for recall

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Reason for recall** | | |
| Adverse reactions | 0 | 1 |
| Foreign matter | 5 | 3 |
| Illegal supply | 1 | 0 |
| Impurity and degradation | 6 | 3 |
| Labelling and packaging | 18 | 7 |
| Micro-organisms | 4 | 2 |
| pH | 0 | 0 |
| Potency | 5 | 3 |
| Sterility | 1 | 0 |
| Other[a] | 17 | 13 |
| Total | 57 | 32 |

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

## 10.2. Medical device recalls

Table 57 Medical device (including IVDs) recalls by reason for recall

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Reason for recall** | | |
| Adverse incidents | 6 | 7 |
| Diagnostic inaccuracy | 82 | 105 |
| Electrical defect | 49 | 28 |
| Illegal supply | 0 | 2 |
| Labelling and packaging | 119 | 89 |
| Mechanical and physical defects | 173 | 169 |
| Software defects | 135 | 109 |
| Sterility | 3 | 14 |
| Other[a] | 44 | 75 |
| Total | 611 | 598 |

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

## 10.3. Biological recalls

Table 58 Biological recalls

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| Recalls to hospital level | 0 | 2 |

# 11. Laboratory testing

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

The Laboratories Branch identifies and prioritises therapeutic goods for testing to fulfil the regulatory compliance and monitoring requirements of the TGA, and the transparency and accountability requirements of government. The testing program also provides flexibility and capacity to provide testing for investigations into problem reports, complaints and urgent public health concerns.

A risk management approach is used, which is consistent with *ISO 31000: Risk Management principals and guidelines,* to identify products with a higher risk of not complying with the required quality standards. This risk based, targeted approach to testing is reflected in the failure rates reported in the table below.

The *Database of TGA Laboratory Testing Results*[1] was launched in the first half of 2017 to provide information to the public about the 2000-plus samples we test each year, and to increase understanding of how our testing program contributes to the regulation of therapeutic goods. Consumers and health professionals can now clearly see which products have been tested by the TGA, whether they passed or failed, and for those that did fail what regulatory action was taken. Providing this information has been an important enhancement to the transparency of the Government's regulatory processes and the vital role of the TGA in ensuring the quality, safety and efficacy of medicines and medical devices for Australian consumers.

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

Table 59 Samples and products tested by type of therapeutic good and percentage which failed

| | | 2015-16 | 2016-17 |
|---|---|---|---|
| | | July to June | |
| **Therapeutic good type** | | | |
| Prescription medicines | Total | 941 | 1,168 |
| | % fail | 0.5 | 0.9 |
| OTC medicines | Total | 47 | 51 |
| | % fail | 19.1 | 13.7 |
| Complementary medicines | Total | 108 | 87 |
| | % fail | 20.4 | 13.8 |
| Medical devices | Total | 114 | 168 |
| | % fail | 29.8 | 31 |
| Contract[a] | Total | 19 | 32 |
| | % fail | 36.8 | 62.5 |
| Unregistered[b] | Total | 467 | 220 |
| | % fail | 76.2 | 63.6 |
| Total samples (excluding AHQ samples) | | 1,696 | 1,726 |
| Total samples[c] | | 2,202 | 2,328 |
| Percentage fail | | 25.5% | 14% |
| Total number of products tested[d] | | 761 | 590 |

[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 60 Samples that failed laboratory testing by reason for July 2016 to June 2017

| | Medical devices | OTC medicines | Prescription medicines | Unregistered products | Complementary medicines | Total |
|---|---|---|---|---|---|---|
| **Reasons** | | | | | | |
| Contamination | 4 | 4 | 2 | 0 | 2 | 12 |
| Formulation | 0 | 0 | 4 | 136 | 6 | 146 |
| Label and packaging deficiencies | 8 | 2 | 0 | 0 | 0 | 10 |
| Performance | 23 | 1 | 4 | 0 | 3 | 31 |
| Physical or mechanical properties | 17 | 0 | 0 | 3 | 0 | 20 |
| Unregistered | 0 | 0 | 0 | 1 | 1 | 2 |
| Total | 52 | 7 | 10 | 140 | 12 | 221 |

Table 61 Batch release and export certification

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Batch releases and certifications** | | |
| Batch release[a] | 401 | 453 |
| Export certification[b] | 59 | 75 |

[a] Evaluation of batch release documentation for vaccines, biotechnology and blood products.

[b] Certification of biological products being exported from Australian manufacturers to overseas markets.

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

Table 62 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 |

Testing on products linked to potential public safety concerns are assigned to the ‘Urgent’ testing category. Urgent testing may impact on the timeframes for priority and routing testing.
Priority is given to testing of products with the highest risk of a quality deficiency.
Compliance against these timeframes is outlined in the table below.

Table 63 Compliance with testing timeframes for July 2016 to June 2017

| | Priority | Total | Percentage |
|---|---|---|---|
| **Therapeutic good type** | | | |
| Medical devices | Routine | 128 | 90% |
| | Priority | 33 | 94% |
| | Urgent | 7 | 43% |
| OTC medicines | Routine | 34 | 56% |
| | Priority | 8 | 100% |
| | Urgent | 9 | 100% |
| Prescription medicines | Routine | 141 | 63% |
| | Priority | 9 | 78% |
| | Urgent | 6 | 83% |
| Complementary medicines | Routine | 56 | 66% |
| | Priority | 31 | 68% |
| | Urgent | 0 | N/A |
| Unregistered products | Routine | 3 | 100% |
| | Priority | 213 | 95% |
| | Urgent | 4 | 100% |

Low numbers of samples within categories may affect compliance percentages.
Samples involving complex biological assays are excluded from the target turnaround timeframes.

# 12. Regulatory compliance

The TGA Regulatory Investigations and Enforcement Unit conducts compliance and enforcement activities against a risk based compliance framework. Using principles of responsive regulation, a range of tools are utilised 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 of protecting public health.

Table 64 Regulatory compliance investigations by final action taken

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| Investigation in progress | 361 | 1,136 |
| **Completed investigations** | | |
| Warned (including destruction) | 946 | 1,973 |
| No offence detected | 185 | 110 |
| Goods released under Personal Import Scheme | 519 | 691 |
| Referred to another agency or department outside Health | 28 | 21 |
| Referred to another branch within the TGA | 10 | 13 |
| Filed for intelligence purposes | 55 | 45 |
| Finalised in a linked file | 11 | 25 |
| Import treated as abandoned goods by Customs | 3 | 8 |
| Recall of goods | 2 | 1 |
| Matters referred to the Commonwealth Director of Public Prosecutions | 1 | 0 |
| Total completed | 1,760 | 2,887 |
| Goods (units) seized and destroyed at the point of importation[a] | N/A | 884,081 |

[a] Due to a change in reporting function, the number of units can now be captured. Units refers to single dosage unit e.g. 1 tablet, 1 capsule, 1 tub of powder or single device.

Table 65 Types of products investigated[a]

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Therapeutic good type** | | |
| Complementary medicines | 463 | 599 |
| Prescription medicines | 1,802 | 4,367 |
| Medical devices | 98 | 166 |
| Homoeopathic medicines | 4 | 36 |
| OTC medicines | 45 | 54 |
| Biological products | 48 | 28 |
| Other | 66 | 119 |
| Total | 2,526 | 5,369 |

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

Table 66 Regulatory compliance investigations by special interest categories

| | 2015-16 | 2016-17 |
|---|---|---|
| | July to June | |
| **Compliance investigation category** | | |
| Unapproved product | 2,110 | 4,855 |
| Counterfeit product | 320 | 326 |
| Parallel import/export | 9 | 28 |
| Manufacture without licence | 1 | 8 |
| Advertising offence | 17 | 19 |
| Traditional Chinese medicines | 7 | 15 |
| Other[a] | 7 | 33 |
| Total | 2,471 | 5,284 |

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

Table 67 Investigations by complainant type and state/territory for July 2016 to June 2017

| Origin | ACT | NSW | NT | QLD | SA | VIC | WA | TAS | Other[a] | Total |
|---|---|---|---|---|---|---|---|---|---|---|
| Complaints resolution | 0 | 9 | 0 | 2 | 0 | 4 | 2 | 0 | 2 | 19 |
| Customs | 4 | 2,373 | 37 | 136 | 12 | 412 | 190 | 0 | 5 | 3,169 |
| External agency | 5 | 7 | 0 | 5 | 2 | 6 | 1 | 0 | 4 | 30 |
| General public | 4 | 13 | 0 | 5 | 0 | 17 | 3 | 0 | 136 | 178 |
| Patient/ practitioner | 0 | 1 | 0 | 1 | 1 | 2 | 0 | 0 | 2 | 7 |
| Sponsor/client | 2 | 9 | 0 | 2 | 1 | 6 | 2 | 0 | 16 | 38 |
| TGA internal | 51 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 52 |
| Total | 66 | 2413 | 37 | 151 | 16 | 447 | 198 | 0 | 165 | 3,493 |

[a] Other includes investigations of anonymous (unknown) origin.

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Reporting and Collaboration Services | 12/09/2017 |

**Therapeutic Goods Administration**

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

Reference/Publication D17-714108