Therapeutic Goods Administration

Stakeholder Survey Report 2025

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Introduction

The Therapeutic Goods Administration (TGA) conducts an annual stakeholder survey to improve the way we work with our stakeholders and to help report on our key performance indicators.

The aim of the survey is to obtain actionable data to help drive our improvement agenda. Just over 2,600 people participated in the survey, including the general public (consumers) and people with a TGA business services account (opt-in stakeholders).

The 2025 survey results were positive overall:

- Awareness of the TGA remains high, with almost two-thirds of Australians having heard of the TGA.
- The TGA continues to be trusted to perform its role ethically and with integrity (82% of all stakeholders), and almost two-thirds of respondents believe the TGA gets the balance right between access to therapeutic goods and safety (64%).
- Approximately 73% of stakeholders agreed that prescription medicines and medical devices are appropriately regulated.
- 73% of stakeholders believed the TGA responds effectively to serious, deliberate and repeated non-compliance.
- Almost all stakeholders found the TGA educational activities they had seen or been involved in at least slightly useful, with most finding them very useful.
- Approximately 69% of stakeholders were satisfied with their experience being involved in a TGA consultation.
- Communicating with the TGA remains a positive experience for the majority of stakeholders (70%), with responses to most enquiries taking 5 days or less.

During the last 12 months, the TGA's Digital Transformation program has made significant progress to improve the digital tools and systems that enable our stakeholders to engage with us. The Health Business Services portal was released and refined, with further improvements scheduled for next year.

The TGA Business Services portal was updated to better help sponsors comply with new vaping reform requirements, and the TGA website continues to be refined based on stakeholder feedback, with recent improvements in search functionality and refined information architecture.

Find out more about the improvements we are making in the <u>What happens next</u> section of this report.

The survey approach

The TGA is part of the Australian Government Department of Health, Disability and Ageing. The 2025 stakeholder survey was developed in conjunction with the department's Market Research Unit.

Why we conduct the survey

The annual stakeholder survey was developed to seek feedback on aspects of the TGA's role and how key stakeholders perceive this role. This feedback helps us improve the way we work with our stakeholders as well as our systems and services.

The survey also contributes to *TGA's Performance Report 2024-25*. This annual self-assessment report evaluates our work against the 3 principles of regulator best practice and the priorities outlined in our <u>TGA Business Plan 2025-26</u>.

The 3 principles are:

- continuous improvement and building trust
- risk based and data driven
- collaboration and engagement.

Sampling methods

Stakeholders were invited to complete the survey using a combination of methods as follows.

Consumers

Market research provider Qualtrics LLC was engaged to survey at least 1,000 Australians aged 18 years and older (actual number of respondents was 1,050). Quotas were applied to the sample to ensure broad representation of the Australian population across age, gender and location. Respondents completed the questionnaire via an online survey platform. This group is referred to as 'consumers' throughout the report.

Fieldwork for the consumer survey was conducted in September 2025. Tables are provided later in this document.

Opt-in stakeholders

Users of the TGA Business Services system were invited to complete the survey. This system is a web-based portal used to conduct transactions with the TGA, including lodging applications for products that require assessment before they can be entered in the Australian Register of Therapeutic Goods (ARTG). As a result, optin respondents are more likely than other stakeholders to be aware of the TGA and the services we provide.

Of the 1,487 opt-in stakeholders who completed the survey, over two-thirds (1,014 respondents) had roles directly associated with the medical products industry, including manufacturers, sponsors and regulatory affairs consultants. The remaining

respondents in the opt-in stakeholder group had a mix of roles, including retailers, consumer representatives, academics and university researchers.

Tables are provided at Appendix B: Opt-in stakeholder results.

Government representatives

We invited state, territory and federal government representatives we work closely with to complete the survey. We received 73 responses from this activity. Given the number of respondents in this cohort is low, this data is not provided in the report's narrative; however, key figures are reported separately at Appendix C: Government representatives' results.

Changes from previous years

Health professionals were not surveyed for the 2025 stakeholder survey due to the small sample size and high costs associated with obtaining data for this cohort. Instead, data from other sources within the Department of Health, Ageing and Disability can be accessed more cost effectively.

Interpreting percentages and tables

Throughout the report, results are presented as whole numbers for ease of reading, with rounding performed at the last stage of calculation. Values from .0 to .4 are rounded down and values from .5 to .9 are rounded up. Therefore, in some instances results may not total 100%. Numbers presented in the appendices' tables are rounded to one decimal point to provide full details.

Questions in the consumer survey were compulsory as respondents received a payment for completing the survey. Questions in the opt-in survey were optional as respondents did not receive a payment. This means some opt-in respondents did not answer every question or only completed part of the survey. Except where stated otherwise, each percentage included in this report is the percentage of respondents who answered the relevant question and not the percentage of the total number of respondents who completed at least part of the survey.

Results tables for stakeholder groups are presented at the end of the report. Tables have not been provided for questions with a low number of responses. Abbreviations used in the results tables are defined in Appendix E: Abbreviations.

Although many questions in the survey were intended for respondents who were aware of the TGA, some questions did not require awareness of the TGA or its functions. Many respondents have provided responses of 'unsure' or 'neither agree nor disagree'. As a result, many questions with low levels of satisfaction may not necessarily indicate an overall negative view when considering responses of 'unsure' or 'neither agree nor disagree'.

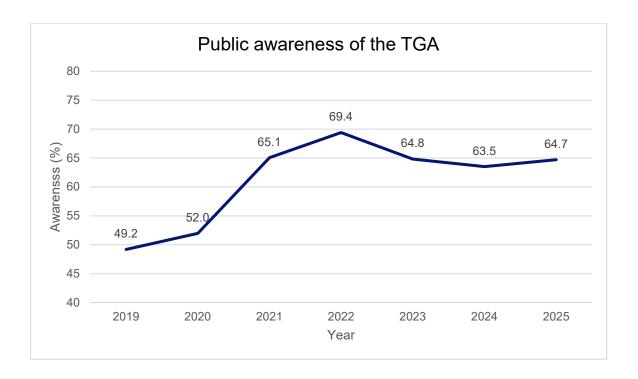
Questions relating to the TGA stakeholder survey can be emailed to tga.education@tga.gov.au.

Overview of results

Awareness of the TGA

Consumers were asked whether they had heard of the TGA before participating in the survey. Almost 2 out of 3 (65%) indicated they had. This is a slight increase from last year (64%) but a decrease from 2022 when awareness of the TGA was at a peak of 69%.

Awareness remains significantly higher than in the surveys conducted in 2020 (52%) and earlier. Consumers aged 18 to 44 years were less likely to have heard of the TGA than those aged 45 years and older (58% compared to 71%) and consumers living in capital cities were more likely to be aware of the TGA than those in remote or regional areas (69% compared to 59%).



Understanding the TGA's regulatory scope

All stakeholder groups were asked what they think the TGA regulates. Respondents were required to select what they believed the TGA regulates from a list of 14 options. Of those options, 9 were correct, such as 'any medicines available in a pharmacy', 'vapes and vaping devices' and 'advertising of medicines and medical devices', and 5 were incorrect, such as 'foods', 'health professionals' and 'medical procedures'.

As in previous years, there is a strong distinction between the 2 stakeholder groups of their understanding of the TGA's regulatory scope, with consumers having lower levels of awareness than opt-in stakeholders.

Consumers have more difficulty identifying that we regulate medical devices (48%), clinical trials (42%), medicinal cannabis (43%), advertising of medicines and medical devices (42%) and medicines compounding (49%).

About 1 in 3 consumers incorrectly believe we regulate health professionals (33%) and medical procedures (33%), with smaller numbers incorrectly believing we regulate veterinary medicines (19%), food (19%), and cosmetics (17%).

Only about a quarter of consumers correctly identified that the TGA regulates vapes and vaping devices (21%), while nearly two-thirds of opt-in stakeholders are aware of this.

Approximately one-third of opt-in stakeholders incorrectly think the TGA regulates veterinary medicines.

Although it would be unreasonable to expect our stakeholders to have detailed knowledge of the TGA's regulatory remit, these results demonstrate that there are opportunities to further improve understanding. For readers who wish to learn more about the scope of TGA regulation, our website includes information on What is not regulated by the TGA.

Getting the balance right

The TGA aims to strike the right balance between safety and access to therapeutic goods. We asked respondents who were aware of the TGA to indicate whether they agree or disagree with the statement, 'The TGA gets the balance right between safety for consumers and access to products'. Almost two-thirds of respondents agreed – 66% of consumers and 63% of opt-in stakeholders. Disagreement with this statement was lower among consumers (8%) than opt-in stakeholders (16%).

This represents an increase of 4% in agreement among consumers from last year. The level of trust from opt-in stakeholders is unchanged from last year, with disagreement up by 2%.

While the results are positive overall, and a level of disagreement is expected given the broad range of therapeutic goods the TGA regulates, we will continue to work to ensure stakeholders are supported and understand our risk-based approach to regulation.

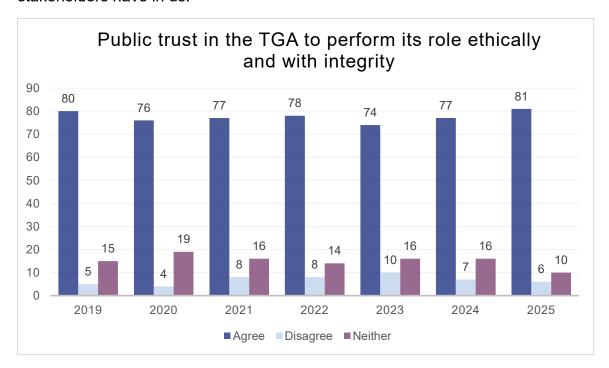
Trust

Respondents who were aware of the TGA were asked to indicate their level of agreement with the statement, 'I trust the TGA to perform its role ethically and with integrity'.

Among consumers, 81% agreed that the TGA acts ethically and with integrity while 6% disagreed. This is up from 77% in 2024 and is at its highest level since 2018.

For opt-in stakeholders, 83% agreed and 8% disagreed. These positive results are consistent with the 2024 survey.

These results demonstrate a continued high level of trust in the TGA among key stakeholder groups, and we will work to maintain the high levels of trust our stakeholders have in us.



Awareness of advertising regulations

The TGA regulates therapeutic goods advertising in Australia, including advertising of unapproved therapeutic vaping goods.

Opt-in stakeholders were asked if they advertise therapeutic goods. Those that did were then asked about their awareness of advertising rules for therapeutic goods and the potential consequences for breaking them.

Among opt-in stakeholders, 37% stated that they advertise or arrange the advertising of therapeutic goods. Of this group, 98% said they were aware of the specific rules for advertising therapeutic goods in Australia and 97% were aware of the potentially serious consequences for breaking these rules, such as fines and court action.

Overall, these results demonstrate a continued very high awareness of the rules around advertising therapeutic goods in Australia.

Readers can learn more about <u>advertising therapeutic goods</u> on our website.

Enforcing the regulations

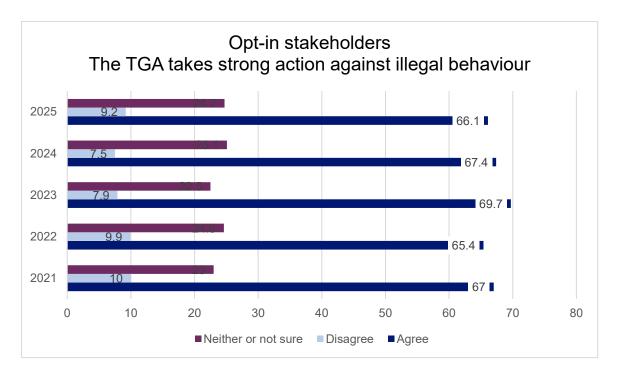
Three statements were included in the survey to measure stakeholder perceptions of the TGA's compliance and enforcement activities.

The first statement aims to measure perceptions of the full range of the TGA's enforcement actions: 'The TGA takes strong action against illegal behaviour'. Agreement with this statement was 67% for consumers (7% disagreed) and 66% for opt-in stakeholders (9% disagreed).

The second relates specifically to the TGA's enforcement of advertising regulations: 'The TGA takes strong action against illegal advertising for health products'. Agreement with this statement was 68% for consumers (7% disagreed) and 63% for opt-in stakeholders (12% disagreed). The high number of consumers responding with 'not sure' or 'neither agreed nor disagreed' (26%) was similar to the other statements.

This was an increase on last year's results, with consumer agreement up 5% and agreement among opt-in stakeholders up 1%.

A third statement aims to gauge whether respondents believe the TGA takes action against serious non-compliance and repeat offenders: 'I am confident the TGA addresses serious, deliberate and repeated non-compliance'. Agreement was higher to this statement, with 72% of consumers agreeing (8% disagreed) and 74% of opt-in stakeholders agreeing (10% disagreed).



Stakeholders were also asked to indicate their agreement or disagreement to a further statement relating to the TGA's regulation of medicines, medical devices and complementary medicines: 'If a safety issue is identified, I am confident that the TGA takes appropriate action'.

Within all stakeholder groups, approximately three-quarters of respondents agreed that the TGA takes appropriate action in relation to medicines and medical devices, a small increase from last year.

For medicines, 75% of consumers and 80% of opt-in stakeholders agreed. The numbers were similar for medical devices, with 75% of consumers and 79% of opt-in stakeholders agreeing.

Consumers and opt-in respondents were slightly less positive regarding action being taken to address safety issues with complementary medicines – 70% of consumers

and 65% of opt-in stakeholders agreed. However, these results are a small increase on last year's when only 66% of consumers and 60% of opt-in stakeholders agreed.

Many respondents across all categories answered 'unsure' or 'neither agree nor disagree'. When taken together, these results suggest that our stakeholders generally believe the TGA takes strong action in response to non-compliance with the therapeutic goods legislation, but there is room for improvement in relation to increasing awareness. We will continue to highlight the work we are doing to ensure compliance with therapeutic goods legislation and the enforcement action we are taking. Our website includes more information about compliance actions and outcomes as well as our Import, Advertising and Supply Compliance Priorities 2023-24.

Perceptions of medicines and medical devices

Stakeholders were asked to rate their agreement with a set of statements on the regulation of:

- prescription and non-prescription medicines (excluding complementary medicines)
- complementary medicines, with examples such as 'vitamins, minerals, herbal or aromatherapy products'
- medical devices, with examples such as 'medical gloves, bandages, neck braces, condoms, pregnancy tests, implants and X-ray equipment'.

Responses from stakeholders indicated a strong level of confidence in the TGA's regulation of medicines and medical devices, with notably weaker confidence in the regulation of complementary medicines. However, this confidence has improved compared with 2024.

Prescription and non-prescription medicines (excluding complementary medicines)

When asked about medicines, 74% of consumers and opt-in stakeholders agreed with the statement that they are appropriately regulated and 79% of consumers and 80% of opt-in stakeholders believed that medicines are manufactured to a high standard. In addition, 82% of consumers and 83% of opt-in stakeholders were confident that the medicines they use are genuine.

Medical devices

When asked about medical devices, 73% of consumers and opt-in stakeholders agreed that medical devices are appropriately regulated, and 78% of consumers and 77% of opt-in stakeholders agreed that medical devices are manufactured to a high standard. In addition, 78% of consumers and 80% of opt-in stakeholders were confident that the medical devices they use are genuine. These results are slightly higher than last year's.

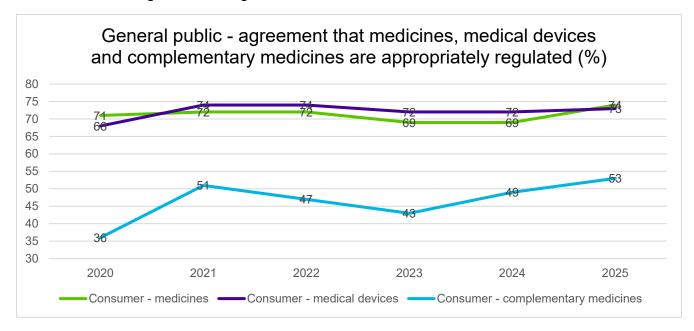
A significant proportion of both consumers and opt-in stakeholders responded 'neither agreed nor disagree', or were not sure to these statements (between 19% and 23% of consumers, and 18% to 20% of opt-in stakeholders). This means

disagreement was quite low to most of the statements. This may be an area where the TGA can increase awareness.

Complementary medicines

The perception of complementary medicines and their regulation was less positive across the 2 stakeholder groups, with 53% of consumers and just 42% of opt-in stakeholders agreeing with the statement that complementary medicines are appropriately regulated. Similarly, 59% consumers and 42% of opt-in stakeholders agreed that they are manufactured to a high standard. Stakeholders were slightly more confident that the complementary medicines they use are genuine, with 64% of consumers and 50% of opt-in stakeholders agreeing.

Despite the lower level of confidence compared with medicines and medical devices, it should be noted that approximately one-third of consumers and opt-in respondents selected 'neither agree nor disagree' or 'unsure'.



Complementary medicines purchased from international websites

Consumers and opt-in stakeholders were asked to rate their level of agreement with the statement 'I believe that complementary medicines purchased from international websites are as safe and effective as those purchased in Australia'. This is a new question for the 2025 survey and aims to provide insights into the public's perception of the safety and efficacy of complementary medicines that are not registered by the TGA.

Responses from both groups showed a low level of trust in complementary medicines purchased from overseas. Only 41% of consumers agreed with the statement and 27% disagreed. Opt-in stakeholders, many of whom have a stronger understanding of the TGA regulatory landscape, were even less positive, with half of respondents (49%) disagreeing that complementary medicines purchased from

international websites are as safe and effective as those purchased in Australia. Only 18% of opt-ins agreed with the statement.

Interestingly, approximately one-third of respondents neither agreed nor disagreed or were not sure (32% of consumers and 33% opt-in stakeholders).

Addressing safety issues (within ccomplementary medicines)

While not all stakeholders may agree that complementary medicines are appropriately regulated, it's important to note that 70% of consumers and 65% of opt in stakeholders agreed with the statement 'If a safety issue is identified, I am confident that the TGA takes appropriate action': Disagreement with the statement was low (between 5% and 8% for all stakeholder groups), with a high proportion of all respondents being unsure. See Enforcing the regulations for more information.

TGA performance

Stakeholders who had previously heard of the TGA were asked to rate their level of agreement with statements about TGA's performance across 4 areas:

- collaboration
- consultations
- education
- contact

Collaboration

Respondents were asked to rate their level of agreement to statements about TGA's collaboration and consultation: 'the TGA provides opportunities to input into key decisions that impact me' and 'the TGA listens to feedback'.

62% of opt-in stakeholders and 56% of consumers agreed that 'the TGA provides opportunities for input into key decisions that impact me', a similar result to last year when 61% of opt-in stakeholders and 53% of consumers agreed. Agreement was slightly lower to the statement 'the TGA listens to feedback', with only half of opt-in stakeholders (49%) and consumers (51%) agreeing, again similar to last year, with 49% of opt-in and 50% of consumers agreeing.

While there was some disagreement with these statements, many of the remaining respondents indicated that they neither agreed nor disagreed or were not sure. Almost a quarter of opt-in stakeholders (23%) and more than a third of consumers (36%) selected 'neither agree nor disagree' or 'unsure' to the statement 'the TGA provides opportunities to input into key decisions that impact me'. For the statement 'the TGA listens to feedback', 41% of consumers and 36% of opt-in stakeholders selected these options. These results are understandable for stakeholders who have not been involved in a TGA consultation or other decision-making process.

These results may also indicate that work needs to continue to ensure stakeholders understand how their feedback is used.

Consultation process

Respondents were asked if they had been involved in one of our consultations in the last 12 months. About 6% of consumers and 22% of opt-in stakeholders participated in a TGA consultation, resulting in a total of 398 stakeholders across the 2 stakeholder groups.

These respondents were then asked about their experience of the consultation process. Of the 438 respondents who participated in a consultation, approximately 76% were satisfied with their experience and 11% were dissatisfied.

Opt-in stakeholders had a satisfaction rate of 67%, with a further 22% selecting 'neither agree nor disagree'. Medical products industry representatives, who make up the majority of the opt-in stakeholder group, were slightly more satisfied with the consultation process (70%), which is an improvement of 7% from last year's result (63%).

Only 57% of opt-in stakeholders believed that the TGA genuinely considered participant input and 14% disagreed. Importantly, 60% agreed that the TGA clearly explained the reasons for the final outcome, up 4% from last year, and 15% disagreed. While not all stakeholders are going to be satisfied with the outcome, the TGA continues to work to improve its consultation communication.

Readers who wish to learn more about TGA consultations, including the outcomes of closed consultations, can find information on our <u>consultation hub</u>.

Contact and interaction

Respondents were asked about their experience and satisfaction with contacting us.

As expected, opt-in stakeholders were much more likely to have contacted or interacted with the TGA in the past 12 months (85%), with 44% reporting that they received a response within 2 days, and over three-quarters (76%) within 5 days. About 12% said it took more than 10 days for the TGA to respond. These numbers represent an improvement in response time since last year, when 73% reported that they received a response within 5 days and 14% said it took more than 10 days.

Overall, most opt-in stakeholders (70%) were satisfied with their experience of communicating with the TGA, up 4% from 2024, while 14% were dissatisfied and 16% were neither satisfied nor dissatisfied. Medical products industry representatives reported slightly higher rates of satisfaction at 72%.

About 28% of consumers indicated they had contacted or interacted with the TGA in the past 12 months. For those who made an enquiry, just over half (55%) received an answer to their enquiry within 2 days, and the majority within 5 days (89%). Only 6% of consumers said the TGA took more than 10 days to respond to them. Overall, most consumers were satisfied with their experience communicating with the TGA (79%), while only 5% were dissatisfied and 16% were neither satisfied nor dissatisfied. This represents a slight improvement on last year's results when 82% of

consumers reported receiving a response within 5 days, and 74% indicated they were satisfied with their experience of communicating with the TGA.

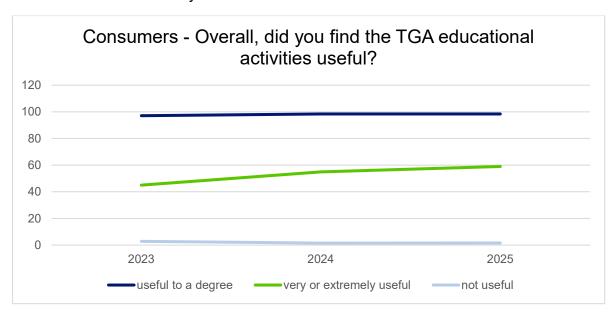
When stakeholders were asked later in the survey if they had seen any improvements to TGA services or systems, 27% of opt-in respondents said they had noticed improvements to 'timeliness or quality of responses to enquiries'. However, respondents regularly mentioned enquiry times as being an issue in the open text feedback, with some respondents not receiving the specific information they needed from the response.

Readers can learn more about our <u>customer services standards</u> and <u>how to contact</u> the TGA on our website. If contact information for a specific area of the TGA is not listed on our website, please use the general TGA information line (1800 020 653 free call within Australia) or email info@tga.gov.au.

Educational activities

The TGA develops and distributes educational material through a range of activities and channels, including events, webinars, email newsletters, social media and advertising campaigns. Stakeholders were asked whether they had seen or been involved in any of these activities in the past 12 months and whether they found them useful.

Almost a quarter of consumers indicated they had seen or been involved in a TGA educational activity in the past 12 months. 16% of consumers had seen a social media campaign or post from the TGA, 8% had attended a TGA webinar, 7% had received a TGA newsletter and 6% had attended a TGA event. Almost all respondents believed the educational activities had been useful to a degree, with almost 3 out of 5 respondents (59%) rating them as 'very' or 'extremely useful', an increase of 4% from last year.



Almost 3 out of 5 (58%) opt-in stakeholders have seen or been involved in TGA educational activities in the past 12 months. The most common was receiving an email newsletter (36%) and attending a webinar (31%). In addition, 17% reported attending a TGA event such as the GMP forum, and 15% saw a social media post or campaign.

These activities were rated as 'very' or 'extremely useful' by 61% of opt-in respondents, up from 55% in 2024, and over 98% believed the educational activities had been useful to some degree, up by 1% from last year.

The positive results demonstrate that the TGA's educational activities continue to meet the needs of most of our stakeholders.

If you would like to receive email newsletters and safety alerts from the TGA, you can subscribe <u>via our website</u>. To see our social media posts and campaigns, follow us on <u>Facebook</u>, <u>X</u>, <u>LinkedIn</u> and <u>Instagram</u>. Our website also provides a list of upcoming and past <u>webinars</u> and <u>events</u>.

Clinical trial information

Opt-in stakeholders were asked if they had used any of the information about clinical trials included on the TGA website in the past 12 months, and if they had, how satisfied they were with the information.

Almost a quarter (24%) of opt-in stakeholders had used the clinical trials information, down 2% from last year. Of these respondents, 71% said they were satisfied with it (down 2% from 2024), 8% were dissatisfied and 21% indicated they were neither satisfied nor dissatisfied with the information.

Clinical trial information is important to many of our stakeholders. When asked about what information they were interested in, over a third of consumers (36%) and opt-in stakeholders (38%) said they were interested in information on clinical trials.

The TGA regulates the use of therapeutic goods supplied in clinical trials in Australia under the therapeutic goods legislation. For more information on clinical trials, see clinical trials.

Stakeholder information interests

Stakeholders were asked about the types of information they would be interested in receiving from the TGA by selecting one or more topics from a list.

Consumers were most interested in:

- Product recalls
- Safety and effectiveness information about medicines and medical devices
- Medicine shortages
- Clinical trials
- Reporting problems or side effects of medicines or medical devices

These 5 topics were of interest to at least one third of respondents and most have remained a priority for consumers for several years.

Opt-in stakeholders were most interested in receiving information on:

- Updated or new regulatory guidance
- Training, workshops or presentations about medicines and medical devices
- Safety and effectiveness information about medicines and medical devices
- Product recalls
- Reporting problems or side effects of medicines or medical devices

Three-quarters of respondents selected 'Updated or new regulatory guidance'. This is also consistent with results from previous years.

This feedback ensures that we continue to provide appropriate information to our stakeholders, with consumers showing a strong preference for safety-related information, and opt-in stakeholders keen to be informed of regulation changes or updates.

Readers who wish to stay updated on the latest safety information should see the <u>safety information</u> on our website. Readers can also subscribe to our <u>safety information email list</u> or follow us on <u>Facebook</u>, <u>X</u>, <u>LinkedIn</u> and <u>Instagram</u> where important safety alerts and other information is posted. We also offer practical information and advice for health professionals through our <u>Safety updates</u>.

Improvements to TGA services

Opt-in stakeholders were asked if they had noticed any improvements to TGA systems or services in the past 12 months and were provided with a list of suggestions. Almost 59% of opt-in stakeholders said they had noticed an improvement, with the most common being 'timeliness or quality of responses to enquiries' (27%) and 'new and updated regulatory information and guidance' (27%). Improvements to the 'TGA website' was mentioned by a quarter of respondents (25%), recognising the work which has been done over the past 12 months.

More information about improvements underway to TGA systems and services is provided in the <u>What happens next</u> section.

Vaping reforms

For the second year, we asked consumers and opt-in stakeholders questions about their awareness of changes to the regulation of vapes and vaping devices.

Responses were similar across both stakeholder groups, with half indicating that they were aware of the changes to the vaping laws in Australia (50% of consumers and 52% of opt-in stakeholders). Over one third of consumers (37%) indicated that were not aware and 14% were unsure. Awareness was highest among 18- to 24-year-olds at 62% and lowest for those over 75 years of age. Only 20% of respondents in remote areas were aware.

This is a decrease from last year's responses, when 78% of consumers indicated that they were aware of the vaping reforms that were implemented. Last year's high score is likely a reflection of the extensive communication strategies that were undertaken by the government to announce the initial changes.

Overall, there is very good awareness of the reforms across the Australian community. However, far fewer respondents are aware of the TGA's role in these reforms (see Understanding the TGA's regulatory scope for more information).

Al as a medical device

New questions were added to this year's survey to gauge respondents' awareness and understanding of artificial intelligence (AI) as a medical device.

There are many health-related apps, websites and internet-based products available that use software and AI to provide information and advice on a person's health and wellbeing. These products are often accessed on a watch, phone, tablet, laptop or other computer. If used for the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury, they are considered a medical device and are likely to be regulated by the TGA.

Stakeholders were asked if they were aware that they may be considered a medical device when they are used for the above purposes. Overall, 41% of consumers were aware that AI products may be considered a medical product. Those aged between 18 and 44 were more likely to be aware (48%), compared with those aged 45 years and older (34%). A similar number (44%) of consumers were aware that if the information provided by these products is wrong it can be reported to the TGA.

As expected, opt-in stakeholders had a higher level of awareness that these products may be considered a medical device (67%). Almost 60% were aware that if there is an issue with the information these products provide, it can be reported to the TGA.

Overall, there is work to be done to raise awareness of the regulation of health-related apps, websites and internet-based products available that are medical devices.

Nicotine pouches

Consumers were asked about their use and awareness of nicotine pouches. The first question was designed to gauge use and interest: 'Do you currently use nicotine pouches, or are you interested in nicotine pouches?'

Only 8% of respondents reported using nicotine pouches, with 16% having never heard of them. Use was highest among people aged 18 to 44 years (13%), and interest was highest for the youngest cohort – those aged 18 to 24 years (15%).

All respondents who had heard of nicotine pouches were asked if they were aware that 'nicotine pouches have not been evaluated for safety, quality or effectiveness by the TGA, and cannot be imported or sold in Australia without TGA approval or a valid written authority or prescription from an Australian health practitioner'. Just over 56%

of respondents were not aware of the regulation of pouches. People aged 18 to 24 years were the most likely to be aware of the regulations (37%).

These results indicate that nicotine pouches are an area of growing interest and use among younger people, and an area where work is required to educate about their risks.

Advertising – special topics

New questions relating to advertising were included in the 2025 survey. Consumers and opt-in respondents were asked about their understanding and perception of the way therapeutic goods are advertised through telehealth services, and when therapeutic goods are referred to by colloquial names.

Advertising through telehealth

Respondents were asked if they believe that 'advertising prescription medicines through telehealth services is potentially harmful'. The survey question included the following explanation of telehealth: 'Telehealth is a consultation with a healthcare provider such as a GP or specialist by phone or video call. Many healthcare providers now offer a telehealth consultation when a physical examination isn't necessary.'

While 38% of consumers agreed that such advertising is potentially harmful, 34% disagreed, and 28% were not sure.

Opt-in stakeholders more strongly agreed, with 67% believing that it is harmful to advertising prescription medicines through telehealth services.

Using colloquial names to advertise

Consumers and opt-in stakeholders who indicated that they were involved in the advertising of therapeutic goods were asked if they 'believe it is misleading to advertise a therapeutic good by using colloquial names, such as advertising medicinal cannabis as "plant-based medicine", "alternative medicine" or "natural medicine"?'

Almost two-thirds of consumers agreed with the statement (64%). Opt-in stakeholders who advertise therapeutic goods had a very high rate of agreement (88%). There was a range of responses within the opt-in stakeholder cohort, with 77% of health professionals agreeing that it is misleading, compared with 91% of medical products industry. This likely reflects the latter's stronger understanding of advertising regulations and the reason such protections are in place.

Written feedback to the TGA

As part of the survey, respondents had the opportunity to provide written feedback to the TGA on areas they believe we can improve. The most common themes are listed in this section, with examples of feedback. Minor typographical errors have been corrected to some of the quotes where the meaning or context is not affected.

Consumers

Feedback from consumers was mostly positive, with many respondents praising the TGA and grateful for the opportunity to learn more about us by completing the survey. Some feedback also highlighted a lack of understanding of the TGA. The following is a sample of comments separated into themes.

Positive

'Overall, the TGA is a key part of Australia's healthcare system, evolving well to meet new challenges.' – male aged 45-54 years from regional NSW.

'This is a necessary company to have and I believe that Australia has one of the best laws for medicine in the world.' – female aged 75 years or older from regional Western Australia.

'I used to work for a health food group and had a lot of dealings with the TGA and was always impressed by their professionalism.' – male aged 55-64 years from Sydney.

'TGA is doing a great job by checking all medication service and products that are in Australia. TGA are good detector and also help remove fake and illicit drugs.' – male aged 25-34 years from Sydney.

'I appreciate their efforts to provide clear guidance on medicines.' – male aged 35-44 years from Sydney.

Lack of awareness / understanding

'As far as I know, TGA covers medication prescribed by a medical doctor. It doesn't cover vitamins and minerals able to be purchased from a grocery store.' – male aged 75 or older from regional Queensland.

'I was not aware of the TGA until I order sunscreen from a New Zealand supplier.' – female aged 35-44 years from Sydney.

'I had no idea it existed, but I'm glad there is a lot of regulation going on with anything related to medicine or medical equipment.' – male aged 25-34 years from Adelaide.

'I was not aware of the TGA. I think they should advertise more and describe the role they perform, it will be very useful if they advertise in medical centers and pharmacies.'– female aged 65-74 years from regional NSW.

'It would be beneficial for the TGA to have a more visible presence in the community so more people are aware of their rights and latest information on the safety of goods and services.' – female aged 65-74 years from Melbourne.

'Need to invest some time and money to ensure all Australians are aware of what you do and where to go to for more info.' – male aged 45-54 years from Canberra.

Lack of trust

'There are times when I see certain things approved in a rush like Covid 19 where I feel they were more interested in what the government wanted than people's health. I doubt their trustworthiness for that reason.' – male aged 65-74 years from Perth.

'I believe the TGA is pointless and our medicine are too highly regulated. It's a joke.' – female aged 55-64 years from regional NSW.

'They are against true healing and just help Big Pharma take in the profits at the expense of real health!!!' – female aged 35-44 years from regional Queensland.

Communication

'Need to use less technical terminology to explain to general audiences.' – female aged 25-34 years from regional Victoria.

'Only feedback is to put more awareness campaigns on social media.' – male aged 25-34 years from regional Victoria.

'Continued transparency, timely communication, and stronger public engagement - especially around emerging technologies like Al-driven health tools and vaping will help build greater trust.' – male aged 35-44 years from regional NSW.

Improvements

'Encouraging emerging technologies, novel therapeutics, and digital health products while maintaining safety standards could strengthen Australia's position as a leader in healthcare innovation.' – male aged 45-54 years from regional NSW.

'Further enhancements in digital platforms, accessibility of resources, and proactive communication would help support both industry and the public. Ongoing commitment to collaboration, innovation, and responsiveness will strengthen trust and confidence in the TGA's work.' – male aged 35-44 years from regional NSW.

'Their efforts to modernize regulations, enforce compliance, and engage stakeholders have improved public trust. Innovations like AI regulation and device identification show forward-thinking leadership. Maintaining timely access to medicines while ensuring safety is vital.' – male aged 45-54 years from Sydney.

'Continued transparency around decision-making, especially in emerging areas like medicinal cannabis and AI-driven health tools, would further strengthen public trust. I appreciate the educational efforts and opportunities for consultation and encourage ongoing engagement with diverse communities to ensure inclusive and responsive regulation.' – male aged 45-54 years from regional NSW.

Approvals and assessments

'While the TGA generally processes applications efficiently, some stakeholders have reported delays in approvals or responses, especially for new therapeutic products.

Exploring ways to streamline review processes could improve user experience.' – male aged 45-54 years from regional NSW.

'Greater transparency in the assessment process and more consistent updates would help industry participants plan effectively. Faster, more streamlined approval pathways for innovative but low risk products could also support timely access for patients without compromising safety standards.' – male aged 25-34 years from regional NSW.

'While maintaining safety and confidence, the TGA should concentrate on enhancing accessibility, openness, and expediting approval procedures.' – male aged 35-44 years from regional NSW.

Consultation / collaboration

'Expanding consultation with healthcare professionals, patients, and industry groups would strengthen collaboration and trust. Overall, the TGA is an essential regulator, but continued efforts to improve efficiency, communication, and accessibility will ensure it remains responsive to future health challenge.' – male aged 25-34 years from regional NSW.

'Continued efforts to streamline regulatory processes, improve clarity in guidance documents, and engage with stakeholders in a timely manner are highly valued.' – male aged 35-44 years from regional NSW.

Artificial Intelligence

'I am not sure how much work the TGA has done to prepare for increased use of AI by people including health professionals. Some sources should be called out if the information is incorrect and dangerous.' – male aged 65-74 from Sydney.

'TGA must oversee those AI platforms that try to suggest medicines to consumers.' – female aged 25-34 from regional Victoria.

Opt-in stakeholders

Enforcement

'TGA holding importers/distributors accountable when incorrect registrations are sold to the public; better sharing of information when products are recalled.' – other, medical devices.

'Better control over devices available online from overseas that do not have ARTG listing and may not work or be harmful to users' – medical product industry sponsor with 1-19 employees.

'Better control of unregistered devices sold on ecommerce sites such as Amazon.' – medical product industry sponsor with 1-19 employees.

'Closing down of medical devices/products being advertised by eBay Australia etc with direct supply through overseas companies who do not have an ARTG listing. This is an unfair obligation, particularly if recalls are required, borne by the legal

ARTG holder. The TGA was originally set up to protect the public however the current policing does not protect the consumer from counterfeit medical products' – medical product industry sponsor and manufacturer with 1-19 employees.

Communication and education

'Better communication between various sections of the TGA and Sponsor' – medical product industry sponsor with 200-599 employees.

'Better phone response and easier access to talk to someone' – medical product industry sponsor and manufacturer with 20-199 employees.

'Clarity of expectations of allied health practitioners in plain language' – health professional.

'eBS portal to be regularly updated with the current data; guideline enquires, increased interaction with the TGA; best practices & templates improved and shared with industry' – medical product industry sponsor with 20-199 employees.

'Case-management model regarding the auditing of medical device applications i.e. status updates, what day in the review the application is it; ideally on eBS; updates on the TGA IT transformation project (milestones, timelines, benefit to industry); clearer clinical evidence guidance for medical devices' – medical product industry sponsor with 1000-1499 employees.

'Assessment times; timeliness or quality of response' – medical product industry sponsor with 20-199 employees.

'Much of the TGA's guidance, policies, and forms are highly complex, making it difficult for small business owners to understand what is required and how to comply. I encourage the TGA to simplify its materials by using clearer language, step-by-step guidance, and more user-friendly systems. Enhanced support for small enterprises through plain-English summaries, checklists, or guided tools would reduce barriers, improve compliance, and allow businesses to engage directly with the TGA without always needing third-party help.'— medical product industry sponsor and manufacturer with 20-199 employees.

Timelines

'Device approval timelines or communication on status' – medical product industry sponsor with 1000-1499 employees.

'Establish clear and expected timelines to improve transparency and provide real-time updates on application statuses' – medical product industry sponsor with 600-999 employees.

'Evaluation times, GMP Clearance backlog cleared.' – medical product industry sponsor with 20-199 employees.

Website

'Updates on TGA website sometimes do not have a summary of updates. Some important updates are not captured in the TGA Industry update newsletter (e.g. updated Essential Principles checklists in September 2025 to include UDI requirements)' – medical product industry sponsor with 600-999 employees.

'More structure to the website with logic to finding guidance documents etc. I find using keywords is the best way to locate a document in the absence of logical navigation pathways to the documents I am looking for. Nothing seems to be catalogued appropriately' – medical product industry manufacturer with 20-199 employees.

'Ongoing consolidation of website to make finding information on TGA website intuitive and clear' – health professional.

Business Services portal

'The Business Services portal can also be challenging to navigate, with language and processes that are not intuitive. This complexity often forces small businesses to hire consultants at significant cost simply to complete what should be routine regulatory tasks.' – medical product industry sponsor and manufacturer with 20-199 employees.

'Optimization of the eBS application portal for user efficiency; Upgrades to the ARTG portal.' – medical product industry sponsor with 200-599 employees.

Applications

'Further integration of GMP processes with the PMAB framework for better coordination and minimise delays in Cat 1 applications.' – medical product industry sponsor with 200-599 employees.

'A clear pathway for including medical devices to the TGA. It is a maze of information and very hard to follow.' – medical product industry sponsor with 1-19 employees

'A significant overhaul of ELF that safeguard the public with accurate information. it is no longer acceptable to just say it's the sponsors fault for incorrect entries to the ARTG, Listings shouldn't validate it not entered property eg Caffeine must have another active ingredient with it, so why does the system validate new Listings where caffeine is the only active entered. Needs to be fixed' – regulatory affairs consultant.

Clinical trials

'Clear documentation about CTN applications in terms of adding sites as they obtain governance approval and any fees if new sites added post initial submission.' – other.

Advertising

'One-page summary of advertising rules for therapeutic goods in Schedules 2,3,4,8. 'Do's and Don't' for product sponsors' – medical product industry manufacturer with 20-199 employees.

'General public has no idea strict limits on medicinal ads & how much leeway for complementary medicines. They'll spend multi-fold Rx costs on complimentary meds that do nothing for them but have great advertising, then can't afford something with actual evidence-base & recommended by their expert doctor which they believe less effective due to permitted advertising differences. Comp med adv stricter please!' – other.

What happens next

The 2025 stakeholder survey results are used to inform the *TGA's Performance Report, July 2024 to June 2025*. The survey results also inform the TGA's ongoing efforts to improve our performance as a regulator and the way we work with our stakeholders. Many of our stakeholders have noted improvements made to TGA systems and services (see Improvements to TGA services).

TGA Digital Transformation

Our Digital Transformation program continues to modernise the digital tools and systems that make it easier for the medical products sector and other stakeholders to complete business transactions, engage with us and find the information they need.

Health Business Services Portal

In 2025–26, the Department of Health, Disability and Ageing will continue making ongoing improvements to the Health Business Services Portal (HBSP), supported by a more secure and varied identity management system. The HBSP will provide a single, secure login for all business users, making it easier to access TGA services as well as other digital services provided across the Department's portfolio. Once logged in, stakeholders will be able to use the modernised TGA Business Services (TBS) portal, with a cloud-based platform designed to streamline your regulatory activities.

TBS portal

Based on industry feedback, the new TBS portal will offer real-time tracking of applications, personalised dashboards, and secure messaging to simplify stakeholders' interactions with us. There will also be simplified navigation, consistent layouts, and increased stability, all aimed at providing a more reliable and user-friendly experience. A beta version of the TBS portal will be available for targeted industry testing in late-2025, with ongoing integration work to ensure a seamless experience across all TGA business areas.

Case management system

Behind the scenes, improvements to the case management system are focused on streamlining workflows and boosting productivity for TGA staff, including the exploration of safe artificial intelligence integration. To support staff, HPRG is transitioning from legacy systems to modern platforms, making it easier for staff to access and use data for analytics and reporting.

Support for vaping reforms

To support the Australian Government's vaping reforms, the TGA has fast-tracked digital improvements to help sponsors comply with new requirements. In February 2025, a new online form was released that allows sponsors to notify the TGA about unregistered therapeutic vaping goods intended for smoking cessation or nicotine dependence, as well as nicotine in solution or other materials to be imported for use in the manufacture of therapeutic vaping goods or other therapeutic products.

The existing Consent to Supply system was updated in March 2025 to enable applications for vaping devices. This means sponsors of vaping devices can now request consent to supply non-included goods that do not comply with the Essential Principles, streamlining the process for these products.

Post market review system

Looking ahead, enhancements to the Post Market Review System are scheduled for release in late February 2026. These improvements will enable more effective reviews of vaping goods, supporting ongoing regulatory oversight and safety monitoring.

TGA Website

We have continued to enhance the TGA website in response to stakeholder feedback and user testing. In 2024–25, we completed over 900 update requests and made significant site improvements. Our website includes <u>more information about these improvements</u>.

We have recently released further changes to the TGA website's navigation and structure, shaped by extensive consultation with both internal and external stakeholders.

We look forward to working closely with our stakeholders to design and deliver these important improvements to make it easier to interact with us. For more information on our goals for the next 12 months, see the TGA's 2025-26 Business Plan.

Guidance and resources

The 'Guidance and resources' section of the TGA website was redesigned to make Guidance clearer, more accessible and reliable.

During the project, Guidance was defined as content explaining the laws and regulations governing the development, manufacturing, marketing, and supply of therapeutic goods in Australia. This has made it clearer to industry about the rules they need to follow. Readers can find more information about these changes on our website.

Appendix A: Consumer results

The tables in this section of the report present results for the consumer sample.

- For more information about the consumer sample, see <a>Sampling methods.
- Tables have not been provided for questions with a low number of responses. For general notes about interpreting results tables, see Interpreting percentages and results tables.
- For definitions of abbreviations, see Appendix D: Abbreviations.

Consumers – demographics

Consumers were asked basic demographic questions, including gender, age and location.

Table 1. Consumers – 'What is your age?'

Age	N	%
18-24	101	9.6%
25-34	202	19.2%
35-44	197	18.8%
45-54	140	13.3%
55-64	164	15.6%
65-74	146	13.9%
75 or older	100	9.5%
Total	1050	100

Table 2. Consumers – 'What is your gender?'

Gender	N	%
Male	522	49.7%
Female	521	49.6%
Non-Binary	6	0.6%
I use a different term	0	0%
Prefer not to say	1	0.1%
Total	1050	100

Table 3. Consumers - 'In which state or territory do you live?'

State	N	%
New South Wales	355	33.8%
Victoria	289	27.5%
Queensland	181	17.2%
South Australia	82	7.8%
Western Australia	101	9.6%
Tasmania	27	2.6%
Australian Capital Territory	13	1.2%
Northern Territory	2	0.2%
Total	1050	100%

Table 1. Consumers - 'Where do you live?'

Region	N	%
Capital city	581	55.3%
Regional city/town	368	35.0%
Regional/rural area	96	9.1%
Remote area	5	0.5%
Total	1050	100%

Consumers – role

Table 5. Consumers – 'Which categories describe your role in the community?' Select all that apply.'

Response	N	%
Consumer	741	70.6%
Carer	170	16.2%
Consumer health representative or advocate	71	6.8%
Patient	188	17.9%
Other	172	16.4%
Total	1342	100%

Consumers – awareness of the TGA

Consumers were asked about their awareness of the TGA.

Table 6. Consumers – 'Had you heard of the Therapeutic Goods Administration (TGA) prior to participating in this survey?'

Response	N	%
Yes	679	64.7%
No	371	35.3%
Total	1050	100%

Table 7. Consumers – 'Do you understand the difference between a medicine or medical device the TGA has approved and one it hasn't?

	N	%
Yes	450	66.3%
No	85	12.5%
Not sure	144	21.2%
Total	679	100%

Consumers – TGA performance

Consumers who were aware of the TGA were asked to indicate their level of agreement with a set of statements about the TGA's performance.

Table 8. Consumers – TGA performance items

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not sure	N
The TGA gets the balance right between safety for consumers and timely access to products	7.5%	2.5%	5.0%	16.6%	45.1%	21.1%	66.1%	9.7%	679
I trust the TGA to perform its role ethically and with integrity	5.9%	2.2%	3.7%	10.3%	45.4%	35.5%	80.9%	2.9%	679
I am confident the TGA addresses serious, deliberate and repeated non-compliance	7.5%	2.5%	5.0%	13.7%	46.1%	26.2%	72.3%	6.5%	679
The TGA takes strong action against illegal behaviour	6.5%	1.8%	4.7%	13.1%	39.2%	27.8%	67.0%	13.4%	679
The TGA takes strong action against illegal advertising for health products	6.5%	2.7%	3.8%	12.7%	40.5%	27.2%	67.7%	13.1%	679
The TGA provides opportunities to input into key decisions that impact me	8.0%	2.2%	5.7%	21.4%	37.1%	18.7%	55.8%	14.9%	679
The TGA listens to feedback	8.0%	2.4%	5.6%	22.7%	33.9%	16.8%	50.7%	18.7%	679

Consumers – understanding of TGA regulatory scope

Consumers were asked what they think the TGA regulates.

Table 9. Consumers – 'What do you think the TGA regulates? Select all that apply.'

Response	N	%*
Medicines prescribed by a doctor (correct)	608	57.9%
Advertising of medicines and medical devices (correct)	460	43.8%
Medicines available in supermarkets and other retail outlets (correct)	543	51.7%
Any medicines available in a pharmacy (correct)	636	60.6%
Medical devices (e.g. bandages and pacemakers) (correct)	501	47.7%
Cosmetics (incorrect)	176	16.8%
Foods (incorrect)	196	18.7%
Health professionals (e.g. Doctors, Nurses, Pharmacists, Allied Health Professionals) (incorrect)	342	32.6%
Veterinary medicines (incorrect)	202	19.2%
Medical procedures (e.g. scans, tests, surgery) (incorrect)	349	33.2%
Clinical trials (correct)	439	41.8%
Medicinal cannabis (correct)	450	42.9%
Medicines compounding (correct)	517	49.2%
Vapes and vaping devices (correct)	224	21.3%

Respondents were able to select multiple options. *Percentage of total sample (N = 1050)

Consumers – perceptions of medicines

Consumers were asked about their perceptions of medicines. This was prefaced with the following instructions and definitions:

Below are some statements about medicines that are available in Australia as prescription medicines and over-the-counter medicines. *Please select one answer per row.*

Table 10. Consumers – perceptions of medicines items

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not sure	N
Medicines are appropriately	8.1%	3.0%	5.0%	13.0%	53.5%	20.0%	73.5%	5.3%	679
regulated									
Medicines are manufactured to a	3.7%	1.8%	1.9%	12.6%	51.4%	28.0%	79.4%	4.3%	679
high standard									
I am confident that the medicines	4.3%	1.9%	2.4%	10.5%	50.6%	30.9%	81.4%	3.8%	679
I use are genuine									
I am confident that the	6.5%	2.2%	4.3%	14.6%	47.7%	26.4%	74.1%	4.9%	679
government monitors medicines									
to identify safety issues									
If a safety issue is identified, I	4.8%	1.8%	3.0%	14.2%	47.8%	27.0%	74.9%	6.2%	679
am confident that the TGA takes									
appropriate action									
I believe that the risks of	6.0%	1.3%	4.7%	16.7%	49.6%	21.3%	71.0%	6.4%	679
medicines are balanced against									
their positive impact									

Consumers – perceptions of complementary medicines

Consumers were asked about their perceptions of complementary medicines. This was prefaced with the following instructions and definitions:

Below are some statements about complementary medicines that are available in Australia, such as vitamins and herbal medicines. *Please select one answer per row.*

Table 11. Consumers – perceptions of complementary medicines

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not sure	N
Complementary medicines are appropriately regulated	12.7%	2.5%	10.2%	22.5%	39.9%	12.6%	52.5%	12.4%	1050
Complementary medicines are manufactured to a high standard	8.8%	1.7%	7.0%	22.1%	42.4%	16.5%	58.9%	10.3%	1050
I am confident that the complementary medicines I use are genuine	6.3%	1.9%	4.4%	21.0%	45.3%	18.7%	64.0%	8.7%	1050
I am confident that the government monitors complementary medicines to identify safety issues	10.4%	2.9%	7.5%	18.8%	42.6%	18.4%	61.0%	9.9%	1050
If a safety issue is identified, I am confident that the TGA takes appropriate action	5.0%	1.9%	3.1%	17.0%	47.0%	22.9%	69.9%	8.1%	1050
I believe that the risks of complementary medicines are balanced against their positive impact	7.5%	2.2%	5.3%	23.3%	44.7%	15.9%	60.6%	8.6%	1050
I believe that complementary medicines purchased from international websites are as safe and effective as those purchased in Australia	27.0%	9.0%	17.9%	21.6%	29.7%	11.1%	40.9%	10.6%	1050

Consumers – advertising of prescription medicines

Consumers were asked about the advertising of prescription medicines through telehealth services.

Table 12. Consumers – "Telehealth" is a consultation with a healthcare provider by phone or video. Many healthcare providers now offer a telehealth consultation. Do you believe that advertising prescription medicines through telehealth services is potentially harmful?"

Response	%	N
Yes	38.2%	401.0
No	34.0%	357.0
Not sure	27.8%	292.0
Total	100%	1050

Consumers – perceptions of medical devices

Consumers were asked about their perceptions of medical devices. This was prefaced with the following instructions and definitions:

Below are some statements about medical devices that are available in Australia. Medical devices include a wide range of products, such as medical gloves, bandages, syringes, blood pressure monitors, implants and X-ray equipment. *Please select one answer per row.*

Table 13. Consumers – perceptions of medical devices

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not sure	N
Medical devices are appropriately regulated	4.2%	1.3%	2.9%	15.0%	52.5%	20.1%	72.6%	8.3%	1050
Medical devices are manufactured to a high standard	3.4%	1.2%	2.2%	13.7%	50.5%	27.2%	77.7%	5.1%	1050
I am confident that the medical devices I use are genuine	3.0%	1.2%	1.7%	13.7%	51.9%	25.8%	77.7%	5.6%	1050
I am confident the government monitors medical devices to identify safety issues	5.8%	1.2%	4.6%	14.9%	50.1%	23.4%	73.5%	5.8%	1050
If a safety issue is identified, I am confident that the TGA takes appropriate action	3.7%	1.3%	2.4%	15.0%	48.7%	26.0%	74.7%	6.7%	1050
I believe that the risks of medical devices are balanced against their positive impact	3.5%	1.6%	1.9%	18.5%	49.3%	21.0%	70.4%	7.6%	1050

Consumers – information interests

Consumers were asked to indicate the types of information they would be interested in receiving from the TGA.

Table 14. Consumers – 'What information are you interested in? Please select all that apply.'

Response	N
Product recalls	409
Safety and effectiveness information about medicines and medical devices	
Reporting problems or side effects of medicines or medical devices	
General information about the TGA	313
Information on travelling with medicines and medical devices	307
News and media releases	288
Accessing medicines and medical devices	279
Updated or new regulatory guidance	229
Medicine shortages	385
Medical device supply disruptions	186
Clinical trials	379
Information on consultations	178
Training, workshops or presentations about medicines and medical devices	142
Vaping regulatory reforms	147
Medicines compounding	170
Medicinal cannabis	251
Other	4
None of the above	125

^{*}Respondents were able to select multiple items.

Consumers – contacting the TGA

Consumers who were aware of the TGA were asked if they had contacted us. Respondents who had were asked how long it took for us to respond and their satisfaction with the experience.

Table 15. Consumer – 'In the last 12 months, have you contacted or interacted with the TGA in any of the following ways'

Response	N	%
By email, phone or online form	103	15.2%
On social media	111	16.3%
Through responding to a TGA consultation and/or submitting	66	9.7%
a response to a public consultation		
Involved in a committee, working group or consultative forum	59	8.7%
Another type of interaction (letter, fax etc)	19	2.8%
None of the above	487	71.7%
Total Count (Answering)	679	

Table 16. Consumers – 'Generally, how long does it take for the TGA to respond to your enquiry/enquiries?'

Length of time	N	%
Immediately or less than 1 day	26	23.2%
1 to 2 days	36	32.1%
3 to 5 days	38	33.9%
6 to 10 days	5	4.5%
More than 10 days	7	6.3%
Total	112	100%

Table 17. Consumers – 'Overall, how satisfied are you with the experience of communicating with the TGA?'

Nett Dissatisfaction	Very dissatisfied	Dissatisfied	Neither	Satisfied	Very satisfied	Nett satisfaction	N
5.4%	3.6%	1.8%	16.1%	49.1%	29.5%	78.6%	112

Consumers – consultations

Consumers who were aware of the TGA were asked about their participation in TGA consultations. Respondents who had participated in a consultation were asked to rate various aspects of the process.

Table 18. Consumers – consultation performance

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	NA/ Too early to say	N
The consultation process made it as easy as possible for me to participate	9.1%	4.5%	4.5%	10.6%	48.5%	31.8%	80.3%	0.0%	66
The timeframes for providing input were long enough	10.6%	3.0%	7.6%	10.6%	50.0%	27.3%	77.3%	1.5%	66
The TGA genuinely considered participant input	6.1%	3.0%	3.0%	16.7%	39.4%	37.9%	77.3%	0.0%	66
The TGA clearly explained the reasons for the final outcome	6.1%	4.5%	1.5%	13.6%	37.9%	40.9%	78.8%	1.5%	66

Table 19. Consumers – 'Overall, how satisfied were you with the consultation process?'

Nett Dissatisfaction	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied	Nett satisfaction	N
3.0%	1.5%	1.5%	16.7%	42.4%	37.9%	80.3%	66

Consumers – TGA educational activities

Consumers were asked to select the types of TGA educational activities they had seen or been involved in over the past 12 months and how useful they found them.

Table 20. Consumers – 'In the last 12 months, have you seen or been involved in any TGA educational activities?'

Response	N	%
Seen a social media campaign or post from	166	15.8%
the TGA		
Attended a TGA event, such as the GMP	67	6.4%
Forum		
Attended a TGA webinar	80	7.6%
Received a TGA email newsletter	72	6.9%
Other, please specify	5	0.5%
None of the above	806	76.8%
Total Count (Answering)	1050	

Table 21. Consumers – 'Overall, did you find the TGA educational activities useful?'

Not at all useful	Slightly useful	Moderately useful	Very useful	Extremely useful	N
1.6%	11.9%	27.5%	38.9%	20.1%	244

Consumer - colloquial names in advertising

All consumers were asked about using colloquial names to advertise a therapeutic good.

Table 22. Consumer – 'Do you believe it is misleading to advertise a therapeutic good by using colloquial names, such as advertising medicinal cannabis as "plant-based medicine", "alternative medicine" or "natural medicine"?'

Response	N	%
Yes	669	63.7%
No	381	36.3%
Total	1050	100%

Consumer - awareness of AI as a medical device

All consumers were asked if they had ever used health-related apps, websites and internet-based products that used software and Artificial Intelligence (AI) to provide information and advice on a person's health and wellbeing.

Table 23. Consumer – 'There are a number of health-related apps, websites and internet-based products that could be using software and Artificial Intelligence (AI) to provide information and advice on a person's health and wellbeing. These products may be accessed on a watch, phone, tablet, laptop or other computer. Have you ever used one of these products??'

Response	N	%
Yes	251	23.9%
No	680	64.8%
Not sure	119	11.3%
Total	1050	100%

Table 24. Consumer – 'Are you aware that these products may be considered a medical device when they are used for the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury?'

Response	N	%
Yes	428	40.8%
No	622	59.2%
Total	1050	100%

Table 25. Consumer – 'Are you aware that if the information provided by these products is wrong or doesn't seem quite right, you can report it to the TGA?

Response	N	%
Yes	466	44.4%
No	584	55.6%
Total	1050	100%

Consumer – vaping and nicotine pouches

All consumers were asked if they were aware of the changes to the vaping laws in Australia.

Table 26. Consumer – 'Are you aware of the changes to the vaping laws in Australia?

Response	N	%
Yes	524	49.9%
No	383	36.5%
Don't know	143	13.6%
Total	1050	100%

Table 27. Consumer – 'Do you currently use nicotine pouches, or are you interested in nicotine pouches?

Response	N	%
I currently use	83	7.9%
I don't use	720	68.6%
I don't use but am interested	78	7.4%
I have never heard of nicotine pouches	169	16.1%
Total	1050	100%

Table 28. Consumer – 'Do you currently use nicotine pouches, or are you interested in nicotine pouches? Response by age groups

Statement	18- 24	25-34	35-44	45-54	55-64	65-74	75 or older
I currently use	11.9%	12.9%	14.2%	5.7%	4.3%	1.4%	0%
I don't use	65.3%	69.8%	64%	70.7%	72.6%	69.9%	67%
I don't use but am interested	14.9%	6.9%	8.6%	10.7%	4.9%	5.5%	1%
I have never heard of nicotine pouches	7.9%	10.4%	13.2%	12.9%	18.3%	23.3%	32%

Consumers who used or were aware of nicotine pouches were asked about their awareness of the regulations.

Table 29. Consumer – 'Are you aware that nicotine pouches have not been evaluated for safety, quality or effectiveness by the TGA, and cannot be imported or sold in Australia without TGA approval or a valid written authority or prescription from an Australian health practitioner?

Response	N	%
Yes	268	30.4%
No	497	56.4%
Don't know	116	13.2%
Total	881	100%

Table 30. Consumer – 'Are you aware that nicotine pouches have not been evaluated for safety, quality or effectiveness by the TGA, and cannot be imported or sold in Australia without TGA approval or a valid written authority or prescription from an Australian health practitioner? Response by age group

Responses	18-24	25-34	35-44	45-54	55-64	65-74	75 or older
Yes	36.6%	31.2%	28.9%	26.4%	16.5%	21.9%	15.0%
No	44.6%	51.5%	45.7%	47.1%	51.8%	45.9%	40.0%
Don't know	10.9%	6.9%	12.2%	13.6%	13.4%	8.9%	13.0%

Appendix B: Opt-in stakeholder results

The tables in this section of the report present results for opt-in stakeholders.

- For more information about the consumer sample, see <u>Sampling methods</u>.
- Tables have not been provided for questions with a low number of responses. For general notes about interpreting results tables, see Interpreting percentages and results tables.
- For definitions of abbreviations, see Appendix D: Abbreviations.

Opt-in stakeholders – demographics

Opt-in stakeholders were asked to identify the industry they belong to. If they selected 'medical products industry' or 'health professional', they were asked further questions about their role.

Table 31. Opt-in stakeholders – 'Which of the following best describes you?'

Role	N	%
Medical products industry	1022	68.7%
Consumer/general public/community	21	1.4%
member		
Consumer representative/advocate	1	0.1%
Australian government	5	0.3%
official/representative		
State or territory government	6	0.4%
official/representative		
Health professional	149	10.0%
Media	0	0.0%
Retailer	50	3.4%
University Researcher/Academic	42	2.8%
Other	191	12.8%
Total	1487	100%

Table 32. Opt-in stakeholders – 'Which category best describes your role as a health professional?'

Role	N	%
Allied health professional	59	40.7%
Complementary healthcare practitioner	7	4.8%
Dental practitioner	8	5.5%
Medical practitioner	21	14.5%
Nursing professional	13	9.0%
Pharmacist	15	10.3%
Other health professional	22	15.2%
Total	145	100%

Table 33. Opt-in stakeholders – 'Which category best describes your role in the medical products industry?'

Role	N	%
Product sponsor (or you work for a company that is a sponsor)	455	44.9%
Product manufacturer (or you work for a company that is a manufacturer)	195	19.2%
Product sponsor and Product manufacturer	259	25.5%
Regulatory affairs consultant	76	7.5%
Industry association representative	5	0.5%
Government affairs representative	0	0.0%
Other, please specify	24	2.4%
Total	1014	100

Table 34. Opt-in stakeholders – 'What type of products do you sponsor?' (product sponsors)

Response	N	%
Prescription medicines	264	37.8%
Over-the-counter medicines	155	22.2%
Complementary medicines	117	16.7%
Medical devices	430	61.5%
Blood and/or tissue products	25	3.6%
Biologicals	97	13.9%
Vaccines	58	8.3%
Software as a medical device (including AI)	74	10.6%
Other, please specify	32	4.6%

Table 35. Opt-in stakeholders – 'What type of products do you manufacture?' (product manufacturers)

Response	N	%
Prescription medicines	116	26.1%
Over-the-counter medicines	57	12.8%
Complementary medicines	65	14.6%
Medical devices	235	52.9%
Blood and/or tissue products	15	3.4%
Biologicals	47	10.6%
Vaccines	25	5.6%
Software as a medical device (including	37	8.3%
AI)		
Other	40	9.0%

Opt-in stakeholders – awareness of the TGA

Table 36. Opt-in stakeholders – 'Had you heard of the Therapeutic Goods Administration (TGA) prior to participating in this survey?'

Response	N	%
Yes	449	98.5%
No	7	1.5%
Total Count (Answering)	456	456

Opt-in stakeholders – understanding of TGA regulatory scope

Opt-in stakeholders were asked what they think the TGA regulates.

Table 37. Opt-in stakeholders – 'What do you think the TGA regulates? Select all that apply.'

Statement	N	%*
Medicines prescribed by a doctor	1,140	92.8%
Advertising of medicines and medical devices	1,104	89.8%
Medicines available in supermarkets and other retail	1,057	86.0%
outlets		
Any medicines available in a pharmacy	1,110	90.3%
Medical devices (e.g. bandages and pacemakers)	1,191	96.9%
Clinical trials	872	71.0%
Vapes and vaping devices	745	60.6%
Medicinal cannabis	1,063	86.5%
Medicines compounding	819	66.6%
Medical procedures (e.g. scans, tests, surgery)	322	26.2%
(incorrect)		
Cosmetics (incorrect)	308	25.1%
Foods (incorrect)	120	9.8%
Health professionals (e.g. Doctors, Nurses,	207	16.8%
Pharmacists, Allied Health Professionals) (incorrect)		
Veterinary medicines (incorrect)	371	30.2%

Respondents were able to select multiple options.

^{*}Percentage of total respondents

Opt-in stakeholders – TGA performance

Opt-in stakeholders who were aware of the TGA were asked to indicate their level of agreement with a set of statements about the TGA's performance.

Table 38. Opt-in stakeholders – TGA performance items

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not sure	N
The TGA gets the balance right between safety for consumers and timely access to products	15.5%	4.9%	10.6%	13.5%	46.3%	16.9%	63.2%	7.8%	1326
I trust the TGA to perform its role ethically and with integrity	7.7%	3.4%	4.3%	7.4%	43.0%	39.6%	82.6%	2.3%	1326
I am confident the TGA addresses serious, deliberate and repeated non-compliance	10.1%	4.0%	6.1%	10.4%	43.6%	29.9%	73.4%	6.1%	1326
The TGA takes strong action against illegal behaviour	9.2%	4.0%	5.2%	14.2%	36.0%	30.2%	66.1%	10.5%	1326
The TGA takes strong action against illegal advertising for health products	11.8%	4.3%	7.5%	13.8%	34.9%	28.0%	62.9%	11.6%	1326
The TGA provides opportunities to input into key decisions that impact me	15.1%	5.7%	9.4%	17.4%	41.7%	19.8%	61.5%	6.1%	1326
The TGA listens to feedback	14.7%	6.5%	8.2%	25.4%	33.7%	15.7%	49.4%	10.5%	1326

Opt-in stakeholders – perceptions of medicines

Opt-in stakeholders were asked about their perceptions of medicines. This was prefaced with the following instructions and definitions:

Below are some statements about medicines that are available in Australia as prescription medicines and over-the-counter medicines. *Please indicate your level of agreement with each statement.*

Table 39. Opt-in stakeholders – perceptions of medicines

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not sure	N
Medicines are appropriately regulated	6.6%	1.7%	4.9%	10.3%	48.6%	25.1%	73.7%	9.4%	1291
Medicines are manufactured to a high standard	2.3%	0.9%	1.4%	8.5%	45.5%	34.3%	79.8%	9.4%	1291
I am confident that the medicines I use are genuine	1.9%	0.7%	1.2%	6.9%	45.6%	36.9%	82.5%	8.8%	1291
I am confident that the government monitors medicines to identify safety issues	5.0%	2.0%	3.0%	9.5%	46.0%	31.6%	77.6%	7.9%	1291
If a safety issue is identified, I am confident that the TGA takes appropriate action	5.1%	2.8%	2.3%	8.3%	45.8%	33.9%	79.7%	6.9%	1291
I believe that the risks of medicines are balanced against their positive impact	5.6%	2.5%	3.1%	11.7%	46.2%	28.9%	75.1%	7.6%	1291

Opt-in stakeholders – perceptions of medical devices

Opt-in stakeholders were asked about their perceptions of medical devices. This was prefaced with the following instructions and definitions:

Below are some statements about medical devices that are available in Australia. Medical devices include a wide range of products, such as medical gloves, bandages, syringes, blood pressure monitors, implants and X-ray equipment. *Please indicate your level of agreement with each statement*.

Table 40. Opt-in stakeholders – perceptions of medical devices

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	N
Medical devices are appropriately regulated	8.4%	2.1%	6.4%	18.7%	57.1%	15.8%	72.9%	1246
Medical devices are manufactured to a high standard	2.9%	0.8%	2.1%	19.9%	57.7%	19.5%	77.2%	1246
I am confident that the medical devices I use are genuine	1.8%	0.5%	1.3%	18.2%	58.0%	22.0%	80.0%	1246
I am confident the government monitors medical devices to identify safety issues	6.8%	1.6%	5.2%	18.7%	54.4%	20.1%	74.6%	1246
If a safety issue is identified, I am confident that the TGA takes appropriate action	6.0%	1.9%	4.1%	15.3%	54.8%	23.9%	78.7%	1246
I believe that the risks of medical devices are balanced against their positive impact	6.2%	1.9%	4.3%	20.1%	55.8%	18.0%	73.7%	1246

Opt-in stakeholders – perceptions of complementary medicines

Opt-in stakeholders were asked about their perceptions of complementary medicines. This was prefaced with the following instructions and definitions:

Below are some statements about complementary medicines that are available in Australia, such as vitamins and herbal medicines. *Please indicate your level of agreement with each statement.*

Table 41. Opt-in stakeholders – perceptions of complementary medicines

Statement	Nett disagree	Strongly disagree	Disagree	Neither A nor D	Agree	Strongly agree	Nett agree	Not sure	N
Complementary medicines are appropriately regulated	20.6%	5.7%	14.9%	19.5%	30.5%	11.5%	42.0%	17.9%	1257
Complementary medicines are manufactured to a high standard	13.3%	3.4%	10.0%	23.5%	28.5%	13.8%	42.3%	20.9%	1257
I am confident that the complementary medicines I use are genuine	10.0%	2.3%	7.7%	21.9%	34.8%	15.3%	50.1%	18.0%	1257
I am confident that the government monitors complementary medicines to identify safety issues	15.7%	3.7%	12.0%	19.4%	33.9%	13.5%	47.5%	17.5%	1257
If a safety issue is identified, I am confident that the TGA takes appropriate action	8.1%	2.9%	5.3%	14.0%	43.9%	20.8%	64.8%	13.1%	1257
I believe that the risks of complementary medicines are balanced against their positive impact	15.7%	3.9%	11.8%	22.6%	31.5%	13.0%	44.5%	17.2%	1257
I believe that complementary medicines purchased from international websites are as safe and effective as those purchased in Australia	48.6%	22.8%	25.8%	14.6%	11.6%	6.6%	18.2%	18.5%	1257

Opt-in stakeholders – information interests

Opt-in stakeholders were asked to indicate the types of information they would be interested in receiving from the TGA.

Table 42. Opt-in stakeholders – 'What information are you interested in? Select all that apply.'

Statement	N	%
Product recalls	644	55.4%
Safety and effectiveness information about medicines and medical devices	673	57.9%
Reporting problems or side effects of medicines or medical devices	558	48.0%
General information about the TGA	549	47.2%
Information on travelling with medicines and medical devices	249	21.4%
News and media releases	485	41.7%
Updated or new regulatory guidance	909	78.2%
Accessing medicines and medical devices	441	38.0%
Medicine shortages	359	30.9%
Medical device supply disruptions	320	27.5%
Clinical trials	444	38.2%
Information on consultations	425	36.6%
Vaping reforms	121	10.4%
Medicines compounding	192	16.5%
Medicinal cannabis	186	16.0%
Training, workshops or presentations about medicines and medical devices	701	60.3%
Other	71	6.1%

Opt-in stakeholders – contacting the TGA

Opt-in stakeholders who were aware of the TGA were asked if they had contacted us. Those who had were asked how long it took for us to respond and their satisfaction with the experience.

Table 43. Opt-in stakeholders – 'In the last 12 months, have you contacted or interacted with the TGA in any of the following ways'

N	%
966	79.1%
49	4.0%
338	27.7%
178	14.6%
137	11.2%
188	15.4%
18	38

Table 44. Opt-in stakeholders – 'Generally, how quickly did the TGA respond to your enquiry/enquiries?'

Length of time	N	%
Immediately or less than 1 day	83	8.5%
1 to 2 days	346	35.2%
3 to 5 days	321	32.7%
6 to 10 days	110	11.2%
More than 10 days	122	12.4%
Total	982	100%

Table 45. Opt-in stakeholders – 'Overall, how satisfied are you with the experience of communicating with the TGA?'

Nett dissatisfied	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied	Nett satisfied	N
14.2%	5.1%	9.1%	16.2%	50.5%	19.1%	69.6%	988

Opt-in stakeholders – consultations

Opt-in stakeholders who were aware of the TGA were asked about their participation in TGA consultations. Respondents who had participated in a consultation were asked to rate various aspects of the process.

Table 46. Opt-in stakeholders – consultation performance

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not applicable / Too early to say	N
The consultation process made it as	9.0%	2.4%	6.6%	13.3%	55.1%	19.6%	74.7%	3.0%	332
easy as possible for me to participate									
The timeframes for providing input	11.8%	3.3%	8.5%	8.5%	58.9%	17.8%	76.7%	3.0%	332
were long enough									
The TGA genuinely considered	14.2%	7.3%	6.9%	18.7%	40.2%	16.3%	56.5%	10.6%	332
participant input									
The TGA clearly explained the	15.2%	6.4%	8.8%	13.3%	44.2%	15.5%	59.7%	11.8%	332
reasons for the final outcome									

Table 47. Opt-in stakeholders – 'Overall, how satisfied were you with the consultation process?'

Nett dissatisfaction	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied	Nett satisfaction	N
12.1%	4.8%	7.3%	21.5%	57.1%	9.4%	66.5%	331

Opt-in stakeholders – TGA educational activities

Opt-in stakeholders were asked to select the types of TGA educational activities they had seen or been involved in over the past 12 months and how useful they found them.

Table 48. Opt-in stakeholders – 'In the last 12 months, have you seen or been involved in any TGA educational activities?'

Educational activity	%
Seen a social media campaign or post by the TGA	14.8%
Attended a TGA event, such as the GMP Forum	16.5%
Attended a TGA webinar	30.9%
Received a TGA email newsletter	35.8%
Other	2.2%
None of the above	42.5%

Table 49. Opt-in stakeholders – 'Overall, did you find the TGA educational activities useful?'

Not at all useful	Slightly useful	Moderately useful	Very useful	Extremely useful	N
2.5%	7.3%	29.7%	47.4%	13.2%	688

Opt-in stakeholders – clinical trials

Opt-in stakeholders were asked if they had used any of the information about clinical trials included on the TGA website, and if they had, how satisfied they were with the information.

Table 50. Opt-in stakeholders – 'In the last 12 months, have you used any of the information about clinical trials on the TGA website?'

Response	N	%
Yes	273	23.5%
No	820	70.6%
Not sure	68	5.9%
Total	1161	100%

Table 51. Opt-in stakeholders – 'Overall, how satisfied were you with the clinical trial information available on the TGA website?'

Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied	N
1.5%	6.6%	21.0%	59.2%	11.8%	272

Opt-in stakeholders – awareness of AI as a medical device

All Opt-in stakeholders were asked if they had ever used health-related apps, websites and internet-based products that used software and Artificial Intelligence (AI) to provide information and advice on a person's health and wellbeing.

Table 52. Opt-in Stakeholders – 'There are a number of health-related apps, websites and internet-based products that could be using software and Artificial Intelligence (AI) to provide information and advice on a person's health and wellbeing. These products may be accessed on a watch, phone, tablet, laptop or other computer. Have you ever used one of these products?'

Response	N	%
Yes	548	44.1%
No	605	48.6%
Unsure	91	7.3%
Total	1244	100%

Table 53. Opt-in Stakeholders – 'Are you aware that these products may be considered a medical device when they are used for the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury?'

Response	N	%
Yes	832	66.9%
No	271	21.8%
Unsure	140	11.3%
Total	1243	100%

Table 54. Opt-in Stakeholders – 'Are you aware that if the information provided by these products is wrong or doesn't seem quite right, you can report it to the TGA?

Response	N	%
Yes	743	59.7%
No	373	30.0%
Unsure	128	10.3%
Total	1244	100%

Opt-in stakeholders – awareness of advertising obligations

Opt-in stakeholders were asked if they advertise therapeutic goods. Advertisers were then asked about their awareness of therapeutic goods advertising rules and the consequences for breaking them.

Table 55. Opt-in stakeholders – 'Do you advertise or have responsibility for the advertising of therapeutic goods?'

Response	N	%
Yes	494	36.8%
No	849	63.2%
Total	1343	100%

Table 56. Opt-in stakeholders – 'Are you aware that there are specific rules for advertising therapeutic goods in Australia?'

Response	N	%
Yes	483	98.0%
No	10	2.0%
Total	493	100%

Table 57. Opt-in stakeholders – 'Are you aware that there are potentially serious consequences for breaking the therapeutic goods advertising rules in Australia, including fines or court action?'

Response	N	%
Yes	479	97.4%
No	13	2.6%
Total	492	100%

Table 58. Opt-in stakeholders – 'Do you believe it is misleading to advertise a therapeutic good by using colloquial names, such as advertising medicinal cannabis as "plant-based medicine", "alternative medicine" or "natural medicine"?'

Response	N	%
Yes	432	88.3%
No	57	11.7%
Total	489	100%

Opt-in stakeholders – telehealth advertising

"Telehealth" is a consultation with a healthcare provider by phone or video. Many healthcare providers now offer a telehealth consultation.

Table 59. Opt-in stakeholders – 'Do you believe that advertising prescription medicines through telehealth services is potentially harmful?'

Response	N	%
Yes	811	66.9%
No	401	33.1%
Total	1212	100%

Opt-in stakeholders – awareness of vaping law changes

Opt-in stakeholders were asked about their awareness of new vaping law changes.

Table 60. Opt-in stakeholders – 'Are you aware of the changes to the vaping laws in Australia?'

Response	N	%
Yes	632	51.8%
No	431	35.4%
Don't know	156	12.8%
Total	1219	100%

Opt-in stakeholders – TGA improvements

Opt-in stakeholders were asked whether they had noticed any improvements to TGA systems or services in the past 12 months and were provided with a list of suggestions.

Table 61. Opt-in stakeholders – 'In the past 12 months, have you seen any improvements to the following TGA services or systems?'

Statement	N	%
Timeliness or quality of responses to enquiries	325	27.4%
Assessment times	201	17.0%
TGA website	291	24.6%
Consultations	104	8.8%
New and updated regulatory information and guidance	319	26.9%
Safety information including recalls, alerts and adverse	234	19.8%
events		
TGA system such as the ARTG, adverse events	228	19.3%
database, online services		
Other (please specify)	27	2.3%
None of the above	490	41.4%

Appendix C: Government representatives

The tables in this section of the report present results for government representatives.

- For more information about the government representatives' sample, see Sampling methods.
- Tables have not been provided for questions with a low number of responses. For general notes about interpreting results tables, see Interpreting percentages and results tables.
- For definitions of abbreviations, see Abbreviations.

Government representatives – demographics

Government representatives were asked whether they worked for the federal Government or a state or territory Government.

Table 62. Government representatives – 'Select the category that describes your role'

Role	N	%
Australian Government	13	17.8%
official/representative		
State or territory Government	47	64.4%
official/representative		
Other, please specify	13	17.8%
Total	73	

Government representatives – understanding of TGA regulatory scope

Government representatives were asked what they think the TGA regulates.

Table 63. Government representatives – 'What do you think the TGA regulates? Select all that apply.'

TBS Statement	N	%
Medicines prescribed by a doctor	60	100.0%
Advertising of medicines and medical devices	56	93.3%
Medicines available in supermarkets and other retail outlets	48	80.0%
Any medicines available in a pharmacy	53	88.3%
Medical devices (e.g. bandages and pacemakers)	60	100.0%
Cosmetics (incorrect)	5	8.3%
Foods (incorrect)	4	6.7%
Health professionals (e.g. Doctors, Nurses, Pharmacists, Allied Health Professionals) (incorrect)	4	6.7%
Veterinary medicines (incorrect)	21	35.0%
Vapes and vaping devices	41	68.3%
Medicinal cannabis	48	80.0%
Medicines compounding	47	78.3%
Medical procedures (e.g. scans, tests, surgery) (incorrect)	5	8.3%
Clinical trials	22	36.7%

Respondents were able to select multiple options. Incorrect refers to an area that TGA doesn't regulate *Percentage of total respondents

Government representatives – TGA performance

Government representatives were asked to indicate their level of agreement with a set of statements about the TGA's performance.

Table 64. Government representatives – TGA performance

Government Stakeholders Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not sure	N
The TGA gets the balance right between safety for consumers and timely access to products	13.0%	1.4%	11.6%	13.0%	59.4%	5.8%	65.2%	8.7%	69
I trust the TGA to perform its role ethically and with integrity	2.9%	0.0%	2.9%	8.7%	50.7%	36.2%	87.0%	1.4%	69
I am confident the TGA addresses serious, deliberate and repeated non-compliance	13.0%	1.4%	11.6%	13.0%	58.0%	7.2%	65.2%	8.7%	69
The TGA takes strong action against illegal behaviour	8.7%	0.0%	8.7%	18.8%	42.0%	11.6%	53.6%	18.8%	69
The TGA takes strong action against illegal advertising for health products	8.7%	0.0%	8.7%	17.4%	39.1%	13.0%	52.2%	21.7%	69
The TGA provides opportunities to input into key decisions that impact me	8.7%	4.3%	4.3%	14.5%	50.7%	21.7%	72.5%	4.3%	69
The TGA listens to feedback	8.7%	2.9%	5.8%	23.2%	42.0%	17.4%	59.4%	8.7%	69

Government representatives – perceptions of medicines

Government representatives were asked about their perceptions of medicines. This was prefaced with the following instructions and definitions:

Below are some statements about medicines that are available in Australia as prescription medicines and over-the-counter medicines. *Please indicate your level of agreement with each statement.*

Table 65. Government representatives – perceptions of medicines

	Nett	Strongly	Disagree	Neither	Agree	Strongly	Nett	Not	N
Statement	disagree	disagree		agree nor		agree	agree	sure	
				disagree					
Medicines are appropriately regulated	14.1%	0.0%	14.1%	9.4%	46.9%	20.3%	67.2%	9.4%	64
Medicines are manufactured to a high	3.1%	0.0%	3.1%	6.3%	56.3%	28.1%	84.4%	6.3%	64
standard									
I am confident that the medicines I use are	1.6%	0.0%	1.6%	3.1%	46.9%	42.2%	89.1%	6.3%	64
genuine									
I am confident that the Government monitors	6.3%	0.0%	6.3%	7.8%	51.6%	25.0%	76.6%	9.4%	64
medicines to identify safety issues									
If a safety issue is identified, I am confident	4.7%	0.0%	4.7%	10.9%	50.0%	25.0%	75.0%	9.4%	64
that the TGA takes appropriate action									
I believe that the risks of medicines are	7.8%	1.6%	6.3%	6.3%	51.6%	23.4%	75.0%	10.9%	64
balanced against their positive impact									

Government representatives – perceptions of medical devices

Government representatives were asked about their perceptions of medical devices. This was prefaced with the following instructions and definitions:

Below are some statements about medical devices that are available in Australia. Medical devices include a wide range of products, such as medical gloves, bandages, syringes, blood pressure monitors, implants and X-ray equipment. *Please indicate your level of agreement with each statement*.

Table 66. Government representatives – perceptions of medical devices

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not sure	N
Medical devices are appropriately regulated	11.7%	1.7%	10.0%	23.3%	56.7%	8.3%	65.0%		60
Medical devices are manufactured to a high standard	6.7%	0.0%	6.7%	20.0%	58.3%	15.0%	73.3%		60
I am confident that the medical devices I use are genuine	0.0%	0.0%	0.0%	21.7%	56.7%	21.7%	78.3%		60
I am confident the Government monitors medical devices to identify safety issues	13.3%	3.3%	10.0%	23.3%	48.3%	15.0%	63.3%		60
If a safety issue is identified, I am confident that the TGA takes appropriate action	3.3%	0.0%	3.3%	18.3%	60.0%	18.3%	78.3%		60
I believe that the risks of medical devices are balanced against their positive impact	1.7%	0.0%	1.7%	28.3%	53.3%	16.7%	70.0%		60

Government representatives – perceptions of complementary medicines

Government representatives were asked about their perceptions of complementary medicines. This was prefaced with the following instructions and definitions:

Below are some statements about complementary medicines that are available in Australia, such as vitamins and herbal medicines. *Please indicate your level of agreement with each statement.*

Table 67. Government representatives – perceptions of complementary medicines

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not sure	N
Complementary medicines are appropriately regulated	24.2%	1.6%	22.6%	22.6%	25.8%	3.2%	29.0%	24.2%	62
Complementary medicines are manufactured to a high standard	17.7%	1.6%	16.1%	22.6%	24.2%	3.2%	27.4%	32.3%	62
I am confident that the complementary medicines I use are genuine	11.3%	0.0%	11.3%	27.4%	27.4%	6.5%	33.9%	27.4%	62
I am confident that the Government monitors complementary medicines to identify safety issues	17.7%	1.6%	16.1%	17.7%	32.3%	9.7%	41.9%	22.6%	62
If a safety issue is identified, I am confident that the TGA takes appropriate action	8.1%	0.0%	8.1%	16.1%	38.7%	16.1%	54.8%	21.0%	62
I believe that the risks of complementary medicines are balanced against their positive impact	16.1%	1.6%	14.5%	27.4%	21.0%	8.1%	29.0%	27.4%	62
I believe that complementary medicines purchased from international websites are as safe and effective as those purchased in Australia	54.8%	21.0%	33.9%	14.5%	9.7%	3.2%	12.9%	17.7%	62

Government representatives – information interests

Government representatives were asked to indicate the types of information they would be interested in receiving from the TGA.

Table 68. Government representatives – 'What information are you interested in? Select all that apply.'

Government Statement	N	%
Product recalls	27	50.0%
Safety and effectiveness information about medicines and medical devices	31	57.4%
Reporting problems or side effects of medicines or medical devices	27	50.0%
General information about the TGA	13	24.1%
Information on travelling with medicines and medical devices	12	22.2%
News and media releases	18	33.3%
Updated or new regulatory guidance	41	75.9%
Accessing medicines and medical devices	22	40.7%
Medicine shortages	26	48.1%
Medical device supply disruptions	22	40.7%
Clinical trials	8	14.8%
Information on consultations	14	25.9%
Vaping reforms	21	38.9%
Medicines compounding	14	25.9%
Medicinal cannabis	19	35.2%
Training, workshops or presentations about medicines and medical devices	20	37.0%
Other	2	3.7%

Government representatives – contacting the TGA

Government representatives who were aware of the TGA were asked if they had contacted us. Those who had were asked how long it took for us to respond and their satisfaction with the experience.

Table 69. Government representatives – 'In the last 12 months, have you contacted or interacted with the TGA in any of the following ways'

Response	N	%
By email, phone or online form	47	79.7%
On social media	1	1.7%
Through responding to a TGA consultation and/or submitting a response to a public consultation	40	67.8%
By involvement in a committee, working group or formal consultative forum	43	72.9%
Another type of interaction (letter, fax etc)	4	6.8%
None of the above	1	1.7%

^{*}Respondents were able to select multiple answers

Table 70. Government representatives – 'Generally, how quickly did the TGA respond to your enquiry/enquiries?'

Length of time	N	%
Immediately or less than 1 day	9	19.1%
1 to 2 days	17	36.2%
3 to 5 days	14	29.8%
6 to 10 days	4	8.5%
More than 10 days	3	6.4%
Total	47	100%

Table 71. State representatives – 'Overall, how satisfied are you with the experience of communicating with the TGA?'

Nett dissatisfied	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied	Nett satisfied	N
4.3%	2.1%	2.1%	21.3%	44.7%	29.8%	74.5%	47

Government representatives – consultations

Government representatives were asked about their participation in TGA consultations. Respondents who had participated in a consultation were asked to rate various aspects of the process.

Table 72. Government representatives - Thinking about the last TGA consultation that you were involved in, please indicate your level of agreement with the following statements: *Select one answer per row.*

Statement	Nett disagree	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree	Nett agree	Not sure	N
The consultation process made it as easy as possible for me to participate	5%	5.0%	0.0%	12.5%	67.5%	15.0%	83%	0.0%	40
The time frames for providing input were long enough	13%	5.0%	7.5%	5.0%	67.5%	15.0%	83%	0.0%	40
The TGA genuinely considered participant input	3%	0.0%	2.5%	22.5%	45.0%	7.5%	53%	22.5%	40
The TGA clearly explained the reasons for the final outcome	5%	0.0%	5.0%	20.0%	37.5%	10.0%	48%	27.5%	40

Table 73. Government representatives – 'Overall, how satisfied were you with the consultation process? *Please select one answer*.'

Nett dissatisfied	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied	Nett Satisfied	N
7.5%	0.0%	7.5%	17.5%	67.5%	7.5%	75.0%	40

Government representatives – educational activities

Government representatives were asked to select the types of TGA educational activities they had seen or been involved in over the past 12 months and how useful they found them.

Table 74. Government representatives – 'In the last 12 months, have you seen or been involved in any TGA educational activities?'

Educational activity	N	%
Seen a social media campaign or post by the TGA	9	15.8%
Attended a TGA event, such as the GMP Forum	8	14.0%
Attended a TGA webinar	22	38.6%
Received a TGA email newsletter	16	28.1%
Other, please specify	2	3.5%
None of the above	22	38.6%

Table 75. Government representatives – 'Overall, did you find the TGA educational activities useful?'

Statement	Not at all useful	Slightly useful	Moderately useful	Very useful	Extremely useful	N
Overall satisfaction	0.0%	2.9%	42.9%	51.4%	2.9%	35

Government representatives – clinical trials

Government representatives were asked if they had used any of the information about clinical trials included on the TGA website, and if they had, how satisfied they were with the information.

Table 76. Government representatives – 'In the last 12 months, have you used any of the information about clinical trials on the TGA website?'

Response	N	%
Yes	8	13.6%
No	50	84.7%
Not sure	1	1.7%
Total	59	100%

Table 77. Government representatives – 'Overall, how satisfied were you with the clinical trial information available on the TGA website?'

Statement	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied	N
Overall satisfaction	0%	0%	12.5%	87.5%	0%	8

Government representatives – working with the TGA

Government representatives were asked to rate their level of agreement with statements about working with the TGA and the impacts of TGA decisions.

Table 79. Government representatives – 'Thinking about the last 12 months, indicate your level of agreement with the following statements as they relate to your role as a government official or representative'

	Nett disag ree	Strongly disagree	Disagree	Neither	Agree	Strongl y agree	Nett agree	Not sure
The TGA proposes regulatory reforms that are evidence-based	8.3%	0.0%	8.3%	14.6%	52.1%	20.8%	72.9%	4.2%
The TGA consults with state and territory Governments on regulatory changes	4.2%	0.0%	4.2%	6.3%	62.5%	16.7%	79.2%	10.4%
The TGA appropriately considers the impact of its regulatory actions and changes on the Government and territories	20.8%	0.0%	20.8%	18.8%	41.7%	8.3%	50.0%	10.4%
The implementation time frames for regulatory changes are adequate	16.7%	2.1%	14.6%	16.7%	47.9%	6.3%	54.2%	12.5%
The TGA appropriately manages risks when implementing regulatory reforms	10.4%	0.0%	10.4%	20.8%	50.0%	6.3%	56.3%	12.5%
Overall I am satisfied with the interactions I have with TGA staff	8.3%	2.1%	6.3%	10.4%	52.1%	29.2%	81.3%	0.0%

Government representatives – TGA improvement

Government representatives were asked whether they had noticed any improvements to TGA systems or services in the past 12 months and were provided with a list of suggestions.

Table 80. Government representatives – 'In the past 12 months, have you seen any improvements to the following TGA services or systems?' Select all that apply.

	N	%
Timeliness or quality of responses to enquiries	12	22.2%
Assessment times	1	1.9%
TGA website	14	25.9%
Consultations	12	22.2%
New and updated regulatory information and guidance	20	37.0%
Safety information including recalls, alerts and adverse events	13	24.1%
TGA system such as the ARTG, adverse events database, online	10	18.5%
services		
Other (please specify)	2	3.7%
None of the above	14	25.9%

Government representatives – telehealth advertising

Table 81. Government representatives – Do you believe that advertising prescription medicines through telehealth services is potentially harmful?

Response	N	%
Yes	38	67.9%
No	5	8.9%
Not sure	13	23.2%
Total	56	100%

[&]quot;Telehealth" is a consultation with a healthcare provider by phone or video. Many healthcare providers now offer a telehealth consultation.

Government representatives – awareness of AI as a medical device

All Government representatives were asked if they had ever used health-related apps, websites and internet-based products that used software and Artificial Intelligence (AI) to provide information and advice on a person's health and wellbeing.

Table 82. Government Stakeholders – 'There are a number of health-related apps, websites and internet-based products that could be using software and Artificial Intelligence (AI) to provide information and advice on a person's health and wellbeing. These products may be accessed on a watch, phone, tablet, laptop or other computer. Have you ever used one of these products?'

Response	N	%
Yes	15	26.8%
No	36	64.3%
Unsure	5	8.9%
Total	56	100%

Table 83. Government Stakeholders – 'Are you aware that these products may be considered a medical device when they are used for the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury?'

Response	N	%
Yes	33	58.9%
No	23	41.1%
Total	56	100%

Government representatives – awareness of advertising obligations

Government representatives were asked if they advertise therapeutic goods. Advertisers were then asked about their awareness of therapeutic goods advertising rules and the consequences for breaking them.

Table 84. Government Stakeholders – 'Are you involved in the advertising of therapeutic goods?'

Response	N	%
Yes	4	7.1%
No	52	92.9%
Total	56	100%

Table 85. Government Stakeholders – 'Do you believe it is misleading to advertise a therapeutic good by using colloquial names such as advertising medicinal cannabis as "plant-based medicine", "alternative medicine" or "natural medicine"?'

Response	N	%
Yes	50	89.3%
No	6	10.7%
Total	56	100%

Government representatives – awareness of changes to vaping laws

Government representatives were asked about their awareness of new vaping law changes.

Table 86. Government representatives – 'Are you aware of the changes to the vaping laws in Australia?'

Response	N	%
Yes	45	80.4%
No	7	12.5%
Don't know	4	7.1%
Total	56	100%

Appendix D: Abbreviations

Column heading abbreviations in results tables

Agreement scales

Abbreviations for agreement scale results tables

Abbreviation	Definition
N	The number of people who responded to an item
Α	The percentage of N who agreed.
SA	The percentage of N who strongly agreed.
Nett A	The percentage of N who agreed or strongly agreed.
Neither	The percentage of N who neither agreed nor disagreed.
D	The percentage of N who disagreed.
SD	The percentage of N who strongly disagreed.
Nett D	The percentage of N who disagreed or strongly disagreed.
NA	Not applicable
NS	Not sure

Satisfaction scales

Abbreviations for satisfaction scale results tables.

Abbreviation	Definition
N	The number of people who responded to an item.
S	The percentage of N who were satisfied.
VS	The percentage of N who were very satisfied.
Nett S	The percentage of N who were satisfied or very satisfied.
Neither	The percentage of N who were neither satisfied nor dissatisfied.
D	The percentage of N who were dissatisfied.
VD	The percentage of N who were very dissatisfied.
Nett D	The percentage of N who were dissatisfied or very dissatisfied.