Australian Government
Department of Health
Therapeutic Goods Administration

Informing TGA education and communication activities

Market research: stage one – qualitative research report

Introduction

In March 2013, qualitative market research was conducted separately with consumers, health professionals and industry to inform the TGA about the best approach to communication and education for stakeholders.

This research incorporated two face to face sessions with consumers, and online discussion groups with each of the following:

- consumers (18 participants)
- potential suppliers—consumers who work within the health and fitness or beauty industries who wish to import and sell low risk products (7 participants)
- health professionals—GPs, specialists and practice managers (9 participants)
- other health professionals—pharmacists, nurses, midwives, dental practitioners, allied health practitioners and complementary healthcare practitioners (16 participants)
- members of the regulated industry—sponsors, manufacturers, regulatory affairs consultants and industry association representatives (28 participants)

Awareness and understanding of the TGA and its role

Key findings on current awareness and understanding of the TGA

All groups were able to identify the TGA as the regulator of therapeutic goods; the majority of participants had heard of the TGA, even if they had not had any direct contact with the organisation. However, the level of understanding of the TGA's role was low. Industry groups and pharmacists demonstrated the highest level of understanding, due to their knowledge of the *Therapeutic Goods Act 1989*, its regulatory and legislative requirements and either indirect or direct contact with the TGA.

In particular, there is considerable 'greyness' around the role of the TGA, including what the TGA actually does, the regulatory process, the complexity of getting goods approved and how the TGA is funded. The term 'therapeutic goods' caused a lot of 'distraction' in the consumer and health professional (GP, surgeon) groups with a lot of time being taken to clarify what is in scope for regulation as a therapeutic good.

'Perceptions' about the TGA are also hampering communication efforts, particularly negative media coverage, which is currently generating misinformation about the TGA and its role. Once participants were told the "TGA story" using language they understand, contextualised in terms of their own experiences and clearly addressing information gaps, there was much wider acceptance about what is reasonable in terms of resourcing, testing and getting products to market quickly and what the TGA can and cannot cover.

Consumers

Awareness

Consumers demonstrated the lowest level of awareness of the TGA, however many were able to name the TGA as the regulatory body for medicines and medical devices. Those with the highest level of awareness were older, had dealt with the TGA through its website to look up specific goods in response to a particular health issue or knew people in the health industry who have dealings with the TGA.

Even among those who could not name the TGA, there was an implicit understanding that therapeutic goods are regulated, and some defaulted instead to potentially better known organisations such as the US FDA and the Australian Sports Anti-Doping Authority (who were 'in the media' at the time of the study because of the peptides in sport issues). However, when prompted, many of these consumers reported that they had heard of the TGA before.

Many people were also unaware that the TGA provides information for consumers, or that they could contact the TGA directly to obtain information or to report an adverse event.

Understanding

While its role was seen as complex and important, consumers do not believe it is well communicated and perceive the TGA as industry-orientated and characterised by 'too much red tape'.

The TGA is seen by some as over-regulating. These participants questioned delays in approvals and getting goods to market, and viewed recalls suspiciously—seeing them as evidence of a possible breakdown in the system. However, others found the delays reassuring and interpreted them as a sign that a thorough analysis is being done before products are released to the market.

Some of the specific issues about which there was uncertainty, included whether or not the TGA (we have used the language of the participants):

- does all its own testing of medicines
- controls doctors' incentives
- provides drug information packaging, including directions on how to take drugs
- makes recommendations about which products are the best or cheapest on the market
- subsidises expensive drugs and recommends which drugs should be subsidised
- tests alternative medicines and over-the-counter medicines, as well as prescription medicines
- deals directly with the general public or only deals with companies.

Potential suppliers

Awareness

Consumers who want to supply therapeutic goods— such as health food retailers, beauticians and fitness trainers—had a slightly higher level of awareness that the TGA is the government body responsible for regulating therapeutic goods. Although few had had direct dealings with the TGA, some regularly used the TGA website to check ingredients and claims either in response to client questions or when looking to supply.

Understanding

Understanding of the role of the TGA among this group was low. They tended to be more literal in their definition of a therapeutic good with the emphasis on therapeutic—e.g. relaxation therapy—although those in the fitness sector demonstrated a more in-depth understanding.

Some of the specific issues about which there were misconceptions, included whether or not:

- the TGA tested all ingredients, including herbal products
- products not yet tested by the TGA were available on the market and could be sold before claims were verified or the product recalled.

Medical professionals

Awareness

General awareness among health professionals of the TGA is high and primarily developed through product recalls disseminated through TGA alerts, information drawn from medical software and databases, and media coverage about recalls and court cases.

Understanding

Understanding of the TGA's role is higher than in the consumer sector in terms of the TGA's legislative role as part of the Department of Health. However, overall knowledge is still superficial, with a level of confusion as to whether the TGA is also responsible for:

- identifying and subsidising certain medicines for PBS inclusion
- the regulation of products such as medical devices or complementary medicines
- testing of products, including complementary medicines

Other health professionals

Awareness

Other health professionals were generally aware that the TGA existed and had heard about the TGA through a variety of sources, including their university studies, the media or actual interaction with the TGA on specific issues.

Understanding

For some there was a gap between their awareness of the TGA and their knowledge of the TGA's actual role and function. The greatest level of understanding was demonstrated by pharmacists. Within their professional and retail roles, as well as through their university studies, pharmacists had a sound understanding of the TGA's role and the checks and balances in place for therapeutic goods.

Pharmacists also had the most complete understanding of what was meant by a therapeutic good compared to others in the health sector, who were either uncertain or had an incomplete understanding.

Industry

Awareness

Not surprisingly, industry awareness of the TGA and its core role is extremely high.

Understanding

The industry sector demonstrated a thorough understanding of the TGA's role in relation to how they regulate the specific therapeutics good they wished to supply in Australia.

Industry has the greatest and most accurate knowledge when defining therapeutic goods due to the frequency of its dealings with the TGA.

Perceptions of the TGA

The following perceptions from the research highlight how the TGA is currently positioned in people's minds and their 'gut reactions' to seeing a reference to the organisation without additional explanatory information. These reactions represent the sum total perceptions and experiences people have of the organisation, and which are built on:

- existing knowledge (whether accurate or inaccurate) of what the organisation does
- emotions associated with any relevant previous experiences
- interpretations of the images, values and beliefs embodied in the look, feel, tone and language used by the organisation.

The words provided in the table below are participants' 'gut reactions' to the TGA. This question was asked at the beginning of each group. The words are not shown in any particular order.

Table 1: Words associated with the TGA

	Consumers (both groups)	Medical professionals	Other health professionals	Industry
Negative	Bureaucratic Slow Incompetent Recalls/mistakes Under communicated Distrusted Unknown	Bureaucratic Slow Under resourced Lack of capacity		Bureaucratic Insular Siloed Underfunded Risk averse Lack of influence Ambiguous Exposed Secretive Unbending Reactive Inconsistent Discourages innovation Rabbit warren
Neutral	Broad Complex	Regulatory standards Compliance	Drugs/testing Product recall Consumer watchdog	Locally misunderstood Good but slow
Positive	Big job Honourable Necessary Important	Enforcement Respected Quality assurance Protection of people and health and safety	Reputation safety/efficacy Quality and safety	Big job Globally respected Committed Professional

Knowledge gaps

Key findings on knowledge gaps

Across the stakeholder groups, participants demonstrated at least a partial, if not complete, lack of knowledge about:

- the TGA's role and function (what it does and doesn't cover) including its history, how it came about, and its remit and powers
- the approval processes, including timelines and evidence-based data to demonstrate and explain the TGA's decision-making processes and how it regulates medicines and devices. In other words, the how and why, including an understanding of Australian requirements compared to other countries, given that many companies have already paid to have their goods approved overseas
- how the TGA is funded and the implications in terms of transparency and accountability, particularly because industry fees fund the TGA
- whether the TGA answers questions from the public (and even from health professionals) and whether they provide a channel to report adverse events or to enquire about medicines and devices.

Suggestions from participants on how to bridge these gaps included:

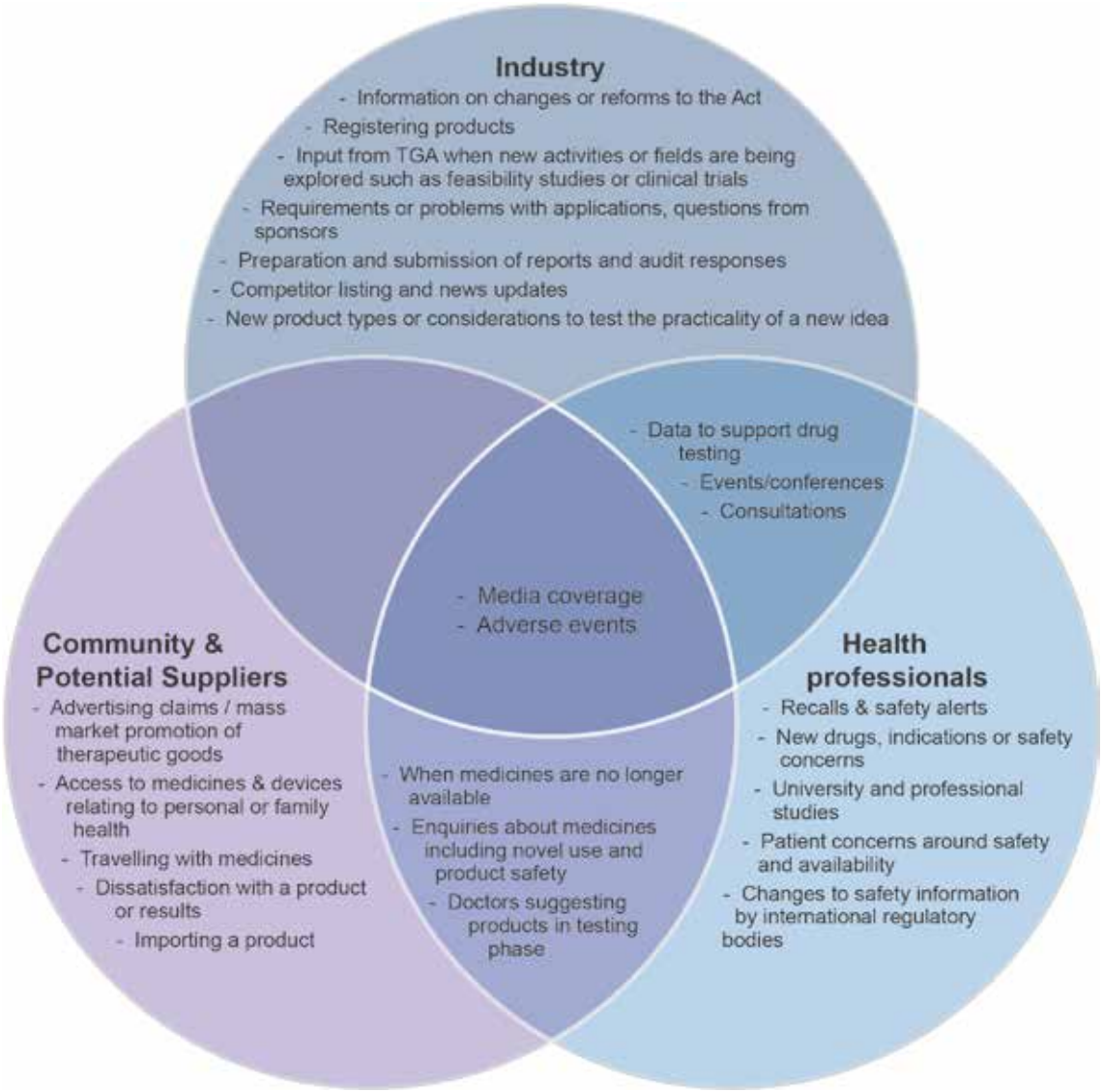
- supplying information on who works at the TGA and their credentials, roles and responsibilities
- providing education for the general public about the TGA and where to go if they have questions or concerns about products, including what they can discuss, who and how to contact, and what reporting channels are available
- increasing information to respond to media reports and clarify the grey areas of the TGA's role, with the TGA providing information first hand rather than consumers hearing third hand commentary by the media.

Specific information needs by each segment are discussed further in this report.

Information seeking

We can target communication and educational material more effectively if we know more about why people want information from the TGA. The chart below illustrates what 'triggers' people to look for information from the TGA.

Figure 2: Information triggers



Information sources

Key findings on current information sources

Multiple sources are used across all stakeholder groups, with no one source seen to meet all information needs.

Consumers

Google searches are most likely to be used by the general public, followed by trusted sources such as their doctor or health professional, friends and family, calling the National Prescribing Service or looking at Choice Magazine.

Potential suppliers

The consumers who are potential suppliers tend to find out information through Google, health professionals, product packaging and then the TGA website. Contact with the TGA by phone or email is generally in response to further information needs or explanations about ingredients, vitamins and questions about if their product needs to go through a TGA 'approval' process.

Medical professionals

Medical professionals and their practice managers are most likely to source information through their clinical software (including MIMs and Phoenix), Google, drug company materials and representatives, the Department of Health, followed by occasional TGA mail items, with little use of the TGA website.

Other health professionals

The information sources this group uses includes manufacturer and product information booklets, therapeutic good representatives, software including eMIMs or eTG, reference books such as the Australian Medicines Handbook, and professional publications.

They also use Google for main ingredients in a medicine, mail and fax notifications, colleagues and local pharmacists, Local Divisions of General Practice (now Medicare Locals) and professional bodies such as the Exercise and Sports Science Association.

Industry

The TGA website is the go-to point for most of industry, followed by direct contact with the TGA when seeking advice and clarification when an immediate response is needed or where further information through the website's centralised portals is not adequate.

The following table summarises the channels currently used by the different stakeholder groups. However, it does not show the degree to which they are used. For example, the TGA website was used by all stakeholder groups, however consumers used it minimally and often only as the result of a Google search.

Table 2: Sources of information

Source	Consumers	Potential suppliers	Medical professionals	Other health professionals	Industry
TGA website	yes	yes	yes	yes	Yes
Media	yes	yes	yes		
Google	yes	yes		yes	
Doctor, pharmacist or other health professional	yes	yes		yes	
Direct notifications from the TGA			yes	yes	yes
Professional or industry bodies and publications			yes	yes	yes
Manufacturer and product information		yes		yes	
Direct contact with TGA		yes			yes
Clinical software (eMIMs)			yes	yes	
Therapeutic goods companies and representatives			yes	yes	
Electronic resources (eTG, Australian Medicines Handbook, Comlaw)				yes	yes
Word of mouth from family and friends	yes				
NPS	yes				
Choice magazine	yes				
Seminars and conferences					yes
Colleagues and consultants					yes

Key findings on new and preferred sources

One key finding that was raised within the health professional and industry groups was that they would prefer to receive messages about recalls and safety issues directly from the TGA before they are published in the media.

Consumers

Consumers noted that they would likely continue to use the same sources they currently access, but that increased awareness of the TGA (i.e. knowing that the TGA is the organisation to contact about therapeutic goods) would also lead to increased use of the TGA website and other direct TGA information sources.

Potential suppliers

Consumers who are also potential suppliers said that they would like to be able to access the following types of communication:

- personal, targeted communications, possibly sent via a trusted source or industry body
- brochures with quick reference materials
- attendance at expos, such as fitness expos

Medical practitioners

Medical practitioners reported that they would prefer to receive information through:

- a stand-alone program on approved items via email alerts
- third party trusted sources, such as local health professional networks and channels

Other health professionals

Many of the other health professionals believe they are already well serviced through existing information sources such as journals, newsletters and guidelines and would contact the TGA by phone or website as needed. However, they suggested that the TGA also provide the following:

- monthly/quarterly newsletter via email or mail (based on Pharmacy Guild format)
- targeted email or fax notices/updates (no more than two per month)
- an A4 notice to hang on the wall with contact details

Industry

Industry was particularly interested in having greater direct contact and face-to-face opportunities with the TGA to ask questions, understand decision making processes, and get consistent advice and ‘answers on the spot’. They also suggested:

- regular forwarding of listed changes to all targeted sponsors as it affects them
- social media

Approach to developing educational materials

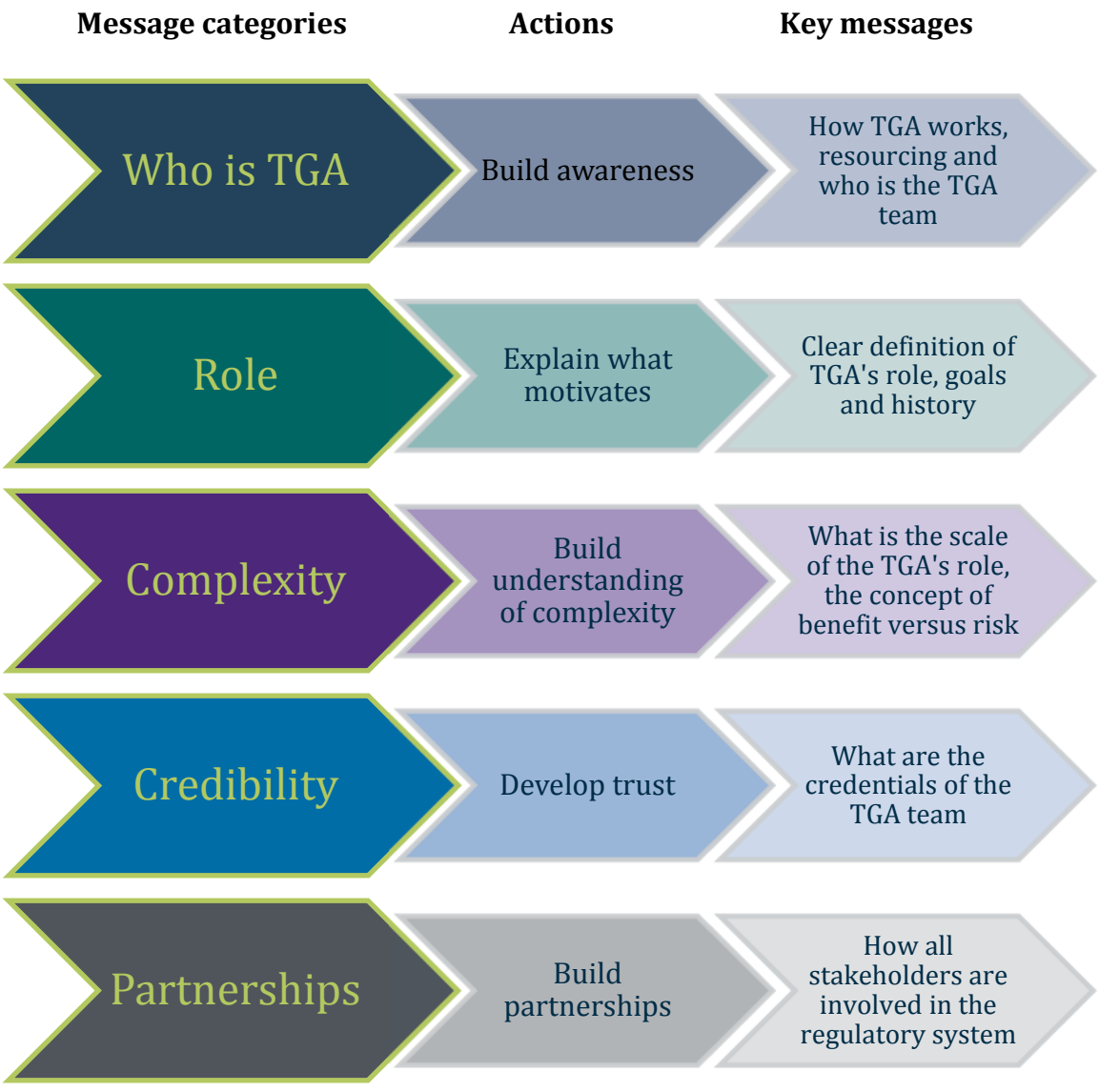
In response to the information received through this research – in particular the knowledge that on receiving good information participants moved from a neutral or negative impression of the TGA to one that recognised the complex work we undertake – five overarching categories of messages have been identified as necessary for future communication and educational materials.

At the broadest level, the TGA needs to:

1. establish credibility and the boundaries within which it operates
2. engage audiences to build on their understanding of the regulatory system and encourage them to participate in the system wherever possible

The following table outlines the five message categories, the action the TGA needs to take in response to each of those categories, and the associated key messages.

Figure 3: Message categories, actions and key messages



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