03 February 2023

To the Therapeutic Goods Administration (TGA) Regulatory Engagement Team,

RE: The TGA's proposed framework of industry education and engagement

Thank you for providing Medicines Australia the opportunity to provide feedback on the TGA's proposed framework of industry education and engagement.

Medicines Australia is the peak body representing the innovative, research-based, medicines industry in Australia. Our members discover, develop and manufacture medicines and vaccines that help people live longer, healthier lives and bring social and economic benefits to Australia.

Please find our responses to the consultation questions below, informed from our Regulatory Affairs Working Group (RAWG) and wider membership.

1. Based on the education needs of your member or client base, what methods of education are best suited to support their engagement?

Each of the proposed learning vehicles, as elaborated in the four pillars, would be appropriate to deliver the educational needs of our Medicines Australia's members. Medicines Australia's RAWG echoed that a mixture of learning opportunities, including interactive ones (virtual or in-person) will be most helpful. These allow for discussion and Q&A in a more collaborative environment.

Additional comments on each delivery method:

a. Interactive group-based online workshops

The online format has proven to be very useful during the recent 'remote working' years. The 'workshop' element and the ability to ask questions would make for more effective learning.

b. Self-paced education via an e-learning platform

Medicines Australia employs online self-paced education programs to teach the Code of Conduct. This is required by pharmaceutical sales representatives, and any person who reviews and approves promotional materials for healthcare professionals or educational materials for consumers, as well as anyone who directly interacts with healthcare professionals. Medicines Australia has received positive feedback for the course and its structure from member and non-member users.

The TGA's SME Assist videos are useful in briefing beginners or lay persons about the functions of the TGA. However, a progressive online course that is broken down into smaller, digestible modules, followed by activities and reflections, will be a more effective learning resource for industry professionals who have regulatory and compliance responsibilities for their companies.

A self-paced education program also allows individuals to track their progress and monitor their learning throughout the course and to choose the most suitable time to complete the modules.

However, depending on how engaging the content is, this method of delivery may be more useful for basic topics, as more complex topics may require live interaction.

c. Presentation via live webinar platform

Same as **a. Interactive group-based online workshops.**

d. Digital content and resources available via the TGA website

Whilst Medicines Australia's membership consists of mostly innovator pharmaceutical companies, patient advocacy groups are also important stakeholders. Members of patient advocacy groups, as well as patients themselves, are becoming more interested in how their treatments are being developed and regulated to ensure they are receiving safe and effective treatments and interventions.

Shorter and/or more readily available content may be more suitable to lay persons with limited technical/industry knowledge. Concise videos with infographics may be a more engaging format than the TGA's SME Assist videos featuring a person speaking at a lectern.

Furthermore, these simpler videos can be useful resources for pharmaceutical company employees who do not have regulatory and compliance responsibilities but need high-level knowledge of the TGA's role and functions.

The effectiveness of these resources will also depend on how easily they are found on the website. Currently, the volume of content on the TGA's website, without a clearer format that aligns to the TGA's organisational structure, make it challenging to navigate and find relevant resources.

e. Other, please specify

The third pillar in the strategy, **Partnered engagement**, should not be limited to 'events'. Ideally, the TGA should proactively offer opportunities for learning opportunities via dialogue, where intricacies of the TGA's perspective and rationale can be discussed.

2. Which TGA topics or functions do your members or clients require additional education?

Medicines Australia's members are innovative pharmaceutical companies with a wide range of product types, including prescription medicines. Many also have manufacturing sites that export products and cover a wide range of submission activities and compliance requirements.

Current staff-turnover rates and new people entering the regulatory affairs field create the need for a wide range of topics that our members and their regulatory teams would find valuable. Practical tools, training and resources for the pharmaceutical industry personnel located on a central platform would be beneficial. These include:

- TGA contacts and organisational structure
- TGA regulation basics and the framework for interactions with TGA and TGA advisory bodies
- Submission and evaluation pathways specific to therapeutic good requirements
- Interplay with Health Technology Assessment bodies and TGA enablers
- How the TGA's regulatory processes intersect with the Pharmaceutical Benefits Advisory Committee's (PBAC) processes and timelines

- Nuances of the PMRP (Prescription medicines registration process)
- How TGA consider and evaluate Quality variations
- Shortages – case studies/best practices
- Good Manufacturing Practice 'unwritten rules/TGA interpretation' of guidelines
- Safety 'unwritten rules/TGA interpretation' of guidelines'
- Audit expectations & learnings – Good Manufacturing Practice, Good Clinical Practice, Good Pharmacovigilance Practice

There are also evolving topics such:

- Companion Diagnostic requirements
- The expectations on the communication and management of Significant Safety Issues
- Other evolving /new regulatory compliance-related issues
- Initiatives for continuous education on regulation of innovative therapies such as cell and gene therapies, medical software etc.

Educational materials should be timed with the delivery of new guidance, and importantly, with adequate communications and lead times to allow industry to better prepare for changes in regulatory requirements.

3. Does your organisation currently provide education on therapeutic goods regulation in Australia? If so, how and why? Please include a link if appropriate.

Medicines Australia does not currently provide any educational materials on the TGA. However, many of our members will provide in-house training as part of on-boarding and staff development. Currently, this can involve referring staff to the TGA website to view the Australian Regulatory Guidelines for Prescription Medicines as well as the other guidelines on the website.

A learning resource platform from the TGA, aimed specifically at developing and understanding and capabilities of regulatory affairs professionals would be beneficial.

4. What do you think of the brand 'TGA Learn'?

The branding is catchy and succinct, but it could be misunderstood as resources for TGA staff, i.e., 'training for TGA'. The broadness of the term 'learn' may raise the expectations of its contents.

5. Over the course of a year how many members or clients seek support from your organisation regarding therapeutic goods regulatory compliance?

Medicines Australia's members have generally sought assistance regarding therapeutic goods regulatory compliance when there are new changes to legislation and guidelines, or when there are supply chain issues and medicines shortages.

As previously stated, the staff-turnover rates mean there are always people entering the industry who require upskilling in TGA requirements. Therefore, there will always be an interest in engaging with well-designed content, educational material, and support for therapeutic regulatory guidance.

Additionally, Medicines Australia's RAWG has a good relationship with the TGA. The regular meetings between RAWG and the Prescription Medicines Authorisation Branch is an excellent forum to raise any compliance issues that emerge, which can then be communicated to the rest of Medicines Australia's membership.

6. Do you have additional feedback or comments you would like to share regarding education and engagement opportunities?

- Medicines Australia and our members support and welcome the establishment of a TGA learning platform. However, the TGA's proposal seems to be very broad in scope if the intention is to cover all areas of industry. Such an undertaking will not be cheap to deliver properly. Given the TGA's current funding situation, there is concern about how this initiative will be funded. It is important for the credibility of the TGA that the TGA Learn is executed well.
- It would be good to know what is driving this initiative for the TGA and to understand what the TGA sees as the need.
- Overall, it is critical to clarify the objective of 'uplift industry knowledge' and distinguish between:
  a. **Basic education:**

     This could be met by online/digital platforms, as is used for Medicines Australia A Code of Conduct training.

  b. **Nuanced challenges faced by more experienced sponsors:**

     For many Medicines Australia member companies who deal with more complex submissions, the challenges are more nuanced, and the answers are difficult to obtain from TGA. Content built on TGA interpretation of guidelines that have caused issues for sponsors, and of real-life regulatory challenges would be useful. Workshops, discussions, and webinars would be more impactful for these, with proper documentation thereafter such as a formal FAQ.

- Finally, the effectiveness of any of these methods could be enhanced by piloting various approaches followed by measurement and assessment of their effectiveness in addressing the intended learning goal. This could have the added benefit of allowing known "pain points" to be fixed first.

Contact:

Constantine Tablan
Policy Analyst
Medicines Australia
constantine.tablan@medicinesaustralia.com.au
17 Denison Street, Deakin ACT 2600