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TGA Learn proposal

AusBiotech is supportive of the *TGA Learn* proposal and its aim to assist stakeholders in successfully navigating the regulatory pathway, support post market compliance activities and reduce barriers to engagement.

AusBiotech is the Australian representative body for one of Australia's most innovative industries with a well-connected network of over 3,000 members in the life sciences sector, which includes biotherapeutics, medical technology (devices and diagnostics) and agricultural biotechnology sectors. This response has been developed together with the AusBiotech's members, and has been developed around the TGA's feedback questions.

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

The proposed *TGA Learn* strategy that is underpinned by four pillars of engagement/education (self-paced online learning modules, online learning events, partnered engagement and digital content partnerships) is warmly welcomed by industry. It offers a valuable combination of in-person and online engagement platforms, which bolsters accessibility given people approach learning in different manners.

Topics that would be beneficial online include process-driven discussion/learning where two-way engagement is not as critical to learning. Where content and discussion is deeper and more nuanced, it is recommended that in-person events and engagement are undertaken – for example, interpreting regulation. This enables questions to be asked and group discussion (and experience) to be leveraged.

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

Education and engagement are required in two areas: building a greater fundamental understanding of the regulatory system and building a depth of knowledge in the application of Australia's regulation.

Topics that could be incorporated into a broader understanding of the regulation include: processes, timeframes, who to reach out to and how to reach out.

To support in-person workshops aiming to up-skill industry in the interpretation of regulatory requirements, it would be beneficial to include content that offers opportunities to build analysis and judgement skills. Highly sought-after course materials include case studies that participants can work through, including real examples and experiences. Some companies have previously faced barriers where scenario-based questions cannot be discussed without first submitting an application; being able to address common scenarios across companies through case studies would help to overcome this hesitancy, and simultaneously ease resources in other departments of the TGA.

As well as case study exercises, utilising blinded examples of success stories would demonstrate and encourage continuous improvement that industry could learn from.

Working through case studies would also reveal 'commonly asked questions', assumptions and myths, thereby offering opportunity for the TGA to address these more broadly through its self-paced online learning.

AusBiotech calls for breadth and depth in topics that further understanding of Australia's regulation requirements throughout end-to-end development, from spin-outs to large companies and working across the life science sectors. This includes the fields of medical technologies (devices and diagnostics), therapeutics and digital health. In addition, education and engagement on emerging technologies such as medicinal cannabis would be beneficial.

The TGA's previous webinars on implementing the EUMDR changes have been noted as valuable, and topical, and would be beneficial to include in the *TGA Learn* library of resources.

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

As an early advocate for the TGA's SME Assist programme, AusBiotech has worked in partnership with the TGA since its launch in 2017 to run and promote its SME Assist workshops. In addition, we are pleased to have Adjunct Professor John Skerritt present each year at the premier industry event, AusMedtech, to share knowledge on the changing landscape and trends being managed by Australia's regulator. We look forward to continuing to partner on these platforms into the future.

Outside of the partnered engagement model, AusBiotech's AusMedtech Advisory Group and AusMedtech Regulatory Affairs Advisory Group have run online webcasts and in-person workshops to upskill the ecosystem on therapeutic goods regulation. AusBiotech does not provide accredited education programmes.

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

The brand 'TGA Learn' suits the objectives of the proposal: to support stakeholders through engagement platforms to successfully navigate the regulatory pathway and post market compliance activities.

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

As a national industry body, we receive approximately 25 enquiries each year. As noted above, AusBiotech represents more than 3,000 members across the life sciences pipeline. Within our membership, there is a diversity in knowledge and experience, as well as in regulatory requirements faced (for example, the regulatory needs for therapeutics companies are different from medtech companies, which is different from technology transfer offices supporting spin-outs). Therefore, the TGA's proposed suite of engagement platforms are welcomed as it offers Australian innovators the opportunity to opt in/out as required by their company/experience/knowledge.

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

AusBiotech values its relationship with the TGA, and the opportunity to continue to partner together to build Australia's regulatory capacity and capability. It looks forward to promoting the new learning initiative to members and industry, and to working together to deliver in-person and online events.

Agnostic to platform and topic, industry encourages the TGA to be clear during its development and marketing on who the audience is for each event and/or module. This includes the sector targeted (for example, therapeutics vs medtech), the size of company and the level of experience.

As the TGA considers the content plan for its 'online learning events', it would be appreciated if it could consider creating a webinar series, rather than/as well as singular/stand alone webcasts, to retain the audience and therefore enable and encourage continuous, ongoing learning. In addition, investing in production would be seen as valuable (rather than recording Webex meetings) as it makes content easier to digest and offers longevity of learning materials.

Yours sincerely,

AusBiotech