Australian Government
Department of Health
Therapeutic Goods Administration

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Consultation submission

This form accompanies a submission on *Consultation: The Regulatory Framework for Advertising Therapeutic Goods November 2016*

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Publishing your submission

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Provided two copies - a complete submission that will not be published and a redacted submission which will be published. The redacted copy can be submitted with the parts of your submission that you **DO NOT** want published marked as 'IN CONFIDENCE'

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- **AND/OR provide details** of content not to be published in the box below.(e.g. "Do not publish pages 3-5)

Additional general information

Please provide the following general information to help with the analysis of stakeholder comments

I am, or I represent:		
Sector		
☐ Blood, tissues, biological	☐ Complementary medicines	☒ IVDs
☐ OTC medicines	☐ Medical devices	☐ Prescription medicines
☐ Advertising	☐ Other (please specify):	
Category		
☐ Consumer	☐ Consumer organisation	☐ Government
☐ Importer	☒ Industry organisation	☐ Institution (e.g. hospital, university)
☐ Laboratory professional	☐ Manufacturer	☐ Professional body
☐ Regulatory affairs consultant	☐ Researcher	☐ Small business
☐ Sole trader	☐ Health professional (please specify):	
☐ Other (please specify):		

We may contact you to ask you for more information or to seek feedback about how the consultation was undertaken. Please tick this box to consent. ☒

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* The *Privacy Act 1988* contains 13 Australian Privacy Principles. Australian Privacy Principle 8.1 provides that:

> Before an APP entity discloses personal information about an individual to a person (the overseas recipient):
>
> (a) who is not in Australia or an external Territory; and
>
> (b) who is not the entity or the individual;
>
> the entity must take such steps as are reasonable in the circumstances to ensure that the overseas recipient does not breach Australian Privacy Principles 2 - 13 in relation to the information. However, where a person consents to the publication of their personal information on the TGA Internet site or the Department of Health Internet site, APP 8.1 will no longer apply in relation to that publication.

For more information about the Australian Privacy Principles, visit the Office of the Australian Information Commissioner's website.

For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Consultation Paper	IVD Australia Position
3.2 Consistency in advertising of medicines and medical devices	**Supports** the implementation of measures that would promote consistency in advertising, provided that these measures are appropriate for advertising IVDs to consumers – including high risk IVDs where appropriate according to intended use.
4. Pre-approval of advertisements	**Endorses**, in principle, a move to a more self-regulatory framework instead of the current statutory pre-approval of advertising of some therapeutic goods. This includes: – Enhanced sanctions and penalties; – Strengthening of post-market monitoring (Recommendation 49); – Advertising claims being consistent with *the intended use* as specified when a product is included in the Australian Register of Therapeutic Goods (Recommendation 38); and – Improving the complaints management process (Recommendation 56). **Stipulates**: – Terminology should be relevant to medical devices; and – Self-regulation should be industry-specific industry associations, particularly if named by government. There should be no opportunity for companies to play organisations off against each other as has been the case previously.
6. Complaints handling	**Endorses** the disbanding the current mechanisms for managing complaints (including the Complaints Resolution Panel) and establishing a new mechanism that is consistent with best practice principles for complaint handling.
6.1 Centralised administration	**Endorses** a single government-led agency to be responsible for receiving and managing complaints relating to advertisements of therapeutic goods. **States** that the biggest concerns re the current system are: – the bias of the CRP against industry that led to inappropriate findings and excessive penalties; – allowing individuals with extreme biases to participate in the CRP; and – allowing serial complainants to flood the system and create a consumer perception of inefficiency; **States** that industry representatives should be an active participant in **all** complaints panels.

Consultation Paper	IVD Australia Position
6.2 2013 Advertising consultation	**Supports** both options from the 2013 consultation. – the TGA to handle all complaints about advertising of therapeutic goods to the public with full and immediate access to all statutory powers; and – self-regulation of complaints handling arrangements.
6.3 Future options	*Model 1 - Commonwealth Agency* **Endorses** the TGA being the single government-led agency to be responsible for receiving and managing complaints relating to advertisements of therapeutic goods. **Stipulates** that industry representatives should be active members of any 'panel'. **Accepts** that consumers would also be involved, but representatives should be pre-vetted and only accepted if they are not members of groups such as Sceptics. *Model 2 - Independent non-Government Authority* **Opposes** both options for this model on grounds of potential bias and outcomes such as those which are a feature of the current system. *Model 3 - Hybrid government and non-government authorities* **Supports** this option, but prefers Model 1. And again: **Stipulates** that industry representatives should be active members of any 'panel'. **Accepts** that consumers would also be involved, but representatives should be pre-vetted and only accepted if they are not members of groups such as Sceptics. **Endorses** that the TGA should take on administration of a new, centralised, advertising complaints handling process **Opposes** an outsourced arrangement, such as through calling for tenders. **Endorses** that the complaints resolution process be used to deal with potentially non-compliant advertisements that are not the subject of an actual complaint.
8. Industry education	**Endorses** development of an education program co-delivered with industry associations and suggests this could be undertaken in conjunction with the Medial Devices Sponsor Information Day.