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To whom it may concern,

Free TV Australia (Free TV) represents all of Australia's commercial free-to-air television broadcasters. Our members provide nine channels of content across a broad range of genres, as well as rich online and mobile offerings. These services are free to view. The value of commercial free-to-air television to all Australians remains high. On any given day, free-to-air television is watched by more than 14 million Australians.

Free TV operates a service called Commercials Advice (CAD). CAD provides classification services for television commercials under the Commercial Television Industry Code of Practice. CAD also provides an information service that aims to direct the attention of advertisers, agencies and production houses to legislative and regulatory requirements relevant to commercials.

Free TV welcomes the opportunity to provide feedback to the Therapeutic Goods Administration (TGA) regarding the options for reform to the regulation of advertising therapeutic goods to the public (the Options Paper).

The primary concern for Free TV and CAD arising out of the Options Paper is the pre-approval scheme.

Broadcasters take both their legal and public safety responsibilities very seriously. Commercial free-to-air broadcasters are subject to a licence condition at clause 6 of Schedule 2 to the *Broadcasting Services Act 1992*, that they must not broadcast a commercial that requires approval under the *Therapeutic Goods Act 1989* (the Act) unless it has been so approved. Similarly, clause 6.5.2 of the Commercial Television Industry Code of Practice requires television commercials for therapeutic goods to be approved by the Australian Self-Medication Industry (ASMI). These requirements are in addition to section 42C of the Act.

The pre-approval scheme is critical for CAD and broadcasters in complying with the Act and the associated rules around advertising of products. It provides an assurance that the relevant advertisements comply with the TGA regime.

This submission is directed towards the options for reform concerning advertising pre-approvals. The other issues set out in the Options Paper are not directly relevant to Free TV.

Pre-approval scheme

Benefits of the pre-approval scheme

When an advertisement for medicines is submitted to CAD for classification, confirmation that the advertisement has been pre-approved by ASMI is required. An advertisement for medicines will

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not be classified unless an ASMI approval is in place and the advertisement complies with any conditions set out in the approval. An advertisement cannot be screened on commercial free-to-air television unless it has been classified.

The pre-approval scheme ensures that advertisements for medicines which can be advertised are assessed by individuals who have appropriate technical and scientific expertise. Assessing compliance with the Therapeutic Goods Advertising Code (TGA Code) and other advertising requirements in the Act is complex and requires specialist knowledge. Pre-approval of advertisements also provides protection for consumers from misleading or false claims about a therapeutic product. The Options Paper does acknowledge that there are some concerns about the current processes; however these can be addressed through improvements to training and administration.

The presence of the pre-approvals scheme also ensures that any advertisements which are prohibited under section 42DL of the Act are not inadvertently published on free-to-air television. This is because an advertisement will not receive a classification from CAD unless it has an ASMI approval (which will not be granted to an advertisement for medicines which cannot be advertised).

The Options Paper notes that there are a number of issues with the current advertising pre-approval scheme, and that cases have arisen where complaints have been upheld by the Panel, even when an advertisement has been pre-approved. There may be scope to improve the current system to make it more robust, by improving training, applying more prescriptive practices around the clearance process, or centralising the pre-approval scheme for all media at a central point. Free TV is supportive of any changes that will make the pre-approvals scheme more efficient and consistent.

The pre-approvals process also carries important public health and safety benefits. The aim of the approvals process is, among other things, to ensure compliance with the Act, Regulations and Code, and to ensure that claims are factual. Without the pre-approvals process, there is a risk that consumers will be exposed to advertisements that breach the advertising requirements, or provide misleading information.

The products that are covered by the pre-approval scheme have the potential to impact on a person's health and wellbeing if used improperly. By regulating and requiring pre-approval for advertisements of such products, the risk to the community is substantially reduced. For these reasons, as set out below, Free TV does not support *Option 5: Removal of the pre-publication scheme*.

A scheme where only 'higher risk' categories of advertisement require pre-approval would also be problematic. The risks associated with misuse of over the counter medications will differ from person to person, depending on their particular medical circumstances, and some medications which are generally low-risk may pose significant risks for some individuals. A general requirement for pre-approval of advertisements is therefore preferred.

Finally, the pre-approval scheme provides assurance and protection for publishers that the advertisements they are publishing have been vetted and approved in accordance with the TGA Code.

Pre-approval scheme should be extended

The Options Paper canvasses the issue of extending the pre-approval scheme to medical devices.

CAD strongly supports this proposal. Extending the pre-approval scheme to include medical devices will apply the same controls to manage the relevant risks to public health and safety as those applied to other therapeutic goods.

There are a number of devices that are advertised directly to the general public, such as portable oxygen concentrators, as well as devices for use within clinics and beauty salons, such as IPL machines. The assessment of these advertisements and their claims requires specialist technical and scientific expertise.

Currently, advertisements for medical devices are reviewed by CAD to ensure that there is no contravention of the TGA Code or associated advertising rules. This process is time consuming, costly and complex for both CAD and advertisers.

For the same reasons, Free TV submits that any reforms to permit advertising of pharmacist-only medicines should also be subject to the pre-approval scheme.

Specific comments on Proposals for reform – pre-approval scheme

The Options Paper sets out the following possible options in relation to pre-approval for publication of advertisements in specified media:

- **Option 1**: Status quo - maintain the current system.
- **Option 2**: Extend the current system to:
    a) include pre-approval for medical devices
    b) cover subscription broadcasting ('narrowcasting') (pay-tv).
- **Option 3**: Limit the current pre-approvals scheme to cover only "higher risk" categories of advertisements.
- **Option 4**: Retain pre-approvals (modified or not as per option 2 or 3) and:
    a) maintain the current pre-approval delegations to industry associations, such as ASMI and CHC (with an appropriate medical devices industry group if option 2(a) is endorsed); or
    b) appoint an independent statutory office holder to undertake pre-approval function; or
    c) TGA to undertake the pre-approval function.
- **Option 5**: Remove the pre-publication approval scheme.

Of the options proposed, Free TV supports Option 2 as a first preference. Options 1 and 4 to retain the pre-approvals scheme are also supported as alternatives.

Option 2 extends the pre-approval scheme to medical devices and also extends the scheme to capture advertising on pay TV. As noted above, Free TV is of the view that advertisements for medical devices should be reviewed and approved before publication by people with appropriate training and expertise. This will provide improved public safety protections, as well as increased certainty in this area for both publishers and advertisers.

Under clause 6 of Schedule 2 to the BSA, pay TV providers are already prohibited from showing an advertisement that has not been pre-approved. Changing the TGA regime to require pre-approval for pay TV should therefore result in no additional cost or change to industry practices.

Free TV is opposed to Options 3 and 5.

One of the identified disadvantages of these options is that they will expose the public to some advertisements that breach advertising requirements. Not only is this a public health risk, it poses an unacceptable level of risk and uncertainty for broadcasters as publishers of such advertisements.

It will result in additional costs for both the advertisers and publishers as they will be required to seek specialist advice about whether the advertisement complies with the relevant provisions of the Act and associated advertising rules. These enquiries will be necessary for publishers to ensure that they will not be in breach, or exposed to any risk of enforcement action.

Summary

Free TV strongly supports a robust and efficient pre-approvals system, which should be extended to devices. This will provide both certainty for publishers and appropriate public safety protections.

Please contact me on (02) 8968 7100 if you require any further information about the matters raised in this submission.

Yours sincerely

Julie Flynn
CEO