The reforms will simplify the regulation of advertising therapeutic products to the public by:

- ceasing pre-approval of advertisements in favour of a more self-regulatory regime;
- implementing a more transparent and efficient complaints management process;
- greater consistency across regulation of advertising of different types of therapeutic goods;
- implementing a formal education program for industry to encourage compliance; and
- broadening and strengthening the TGA’s investigation and enforcement powers.

What is the issue?

There is general consensus that the current advertising framework for therapeutic goods is complex and inconsistencies exist for advertising to consumers depending on product type, advertising media and form of advertising, for example:

- Some advertisements for non-prescription medicines require pre-approval (those in free-to-air broadcasting and magazines) while others do not require pre-approval (those on the internet);
- The agency to which a sponsor must apply for pre-approval is dependent on the advertising media, and two separate applications may be required for advertising the same product;
- Medical device advertising does not require pre-approval and all medical devices can be advertised to consumers – even the highest-risk devices;
- The complaints process often involves duplication of effort and does not enable timely resolution of breaches;
- The current sanctions and penalties do not provide an appropriate deterrent for non-compliant advertising.

Improving consistency and removing pre-approvals

The removal of pre-approval requirements to enable an industry self-regulatory regime will bring therapeutic goods advertising in line with other products, and reduce unnecessary regulatory burden on sponsors. Potential risks from removing pre-approvals will be mitigated by increased sponsor education, improved complaints management and stronger penalties and sanctions for non-compliance, potentially including injunctive powers.

Advertising complaints management

The reforms will see a single agency empowered to receive and triage complaints on the advertising of therapeutic products to the public. This approach to complaints management will reduce complexity and encourage greater consistency in decision-making, benefiting consumers and industry alike. A new complaints management process will require careful design in consultation with consumer groups, health care professionals, industry and other affected stakeholders.

Formal sponsor education program

An education program will be developed for sponsors. It could potentially be co-delivered with industry associations and provide information and tools to assist them in achieving compliance with advertising requirements under a new regulatory framework.

Formal education has the potential to improve compliance and promote greater quality and consistency of advice provided to sponsors on advertising requirements and to help manage the public health risks associated with inappropriate advertising.

Broader and stronger enforcement and compliance powers

Broadening and strengthening enforcement and compliance powers will benefit consumers through deterring inappropriate and misleading advertising of therapeutic products.

Benefits of reforming the advertising framework

The intention of reforms to the regulation of therapeutic goods advertising is to increase safety for consumers by reducing the incidence of misleading advertising. This will be facilitated by improved public confidence in the complaints management process.

Removal of the involvement of government in the pre-approval process for advertising will reduce regulatory and administrative burden for industry but will not preclude industry bodies offering a self-regulatory model should they wish to do so. Compliance with the therapeutic goods advertising requirements will be managed and enforced more effectively (through a strengthened compliance framework), improving consumer and health professional confidence and reducing risks to consumers from exposure to non-compliant advertising.