

	Existing system Australia	Model approved by the Interim Ministerial Council	Differences to model proposed by the IAC	Existing System New Zealand
Standard for advertising	<p>The Therapeutic Goods Advertising Code is applied as standard for all advertisements directed to consumers. The main focus of the Code is the advertising of medicines and it is legally underpinned in the therapeutic goods legislation. Changes to the Code must be approved by the Minister for Health on the advice of the National Manager of the TGA.</p>	<p>The ANZ Therapeutic Products Advertising Code is to be applied as the standard for all advertisements of therapeutic products (directed to consumers and healthcare practitioners) which would be legally underpinned in legislation. While the Key Advertising Principles apply to all advertisements, the ANZ Therapeutic Products Advertising Code tailors certain requirements for the advertising of medical devices and for advertisements directed to healthcare practitioners.</p> <p>The Key Advertising Principles and the Advertising Requirements are to be set out in the therapeutic products legislation. Any changes to these principles or requirements would require approval by the Ministerial Council. Changes to the Code will require approval by the Managing Director.</p>	<p>The IAC recommended that the Advertising Code not be a legislative instrument which is disallowable.</p> <p>The Interim Ministerial Council did not accept this recommendation.</p>	<p>The Advertising Standards Authority (ASA) is responsible for developing and maintaining the Code for Therapeutic Advertising. While Medsafe is consulted on any proposed changes to the Code, the Code is not linked to the <i>Medicines Act 1981</i>. However, the requirements of the Code are broadly consistent with the requirements of the Act.</p> <p>On 1 February 2005, a new Code was given effect which is based on the proposed ANZ Therapeutic Products Advertising Code.</p>

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<p>Governance structures</p>	<p>The Therapeutic Goods Advertising Code Council with 12 members and 5 observers (as a co-regulatory council) is established under the <i>Therapeutic Goods Act 1989</i>. It makes recommendations to the Minister (through the National Manager) on proposed changes to the Code.</p>	<p>As a statutory expert advisory committee, the Advertising Council will provide advice to the Joint Agency on the operation of the Advertising Code for both Australia and NZ. The Council will also monitor the effectiveness of the processes associated with the controls on therapeutics advertising in Australia and New Zealand and provide feedback to the Joint Agency.</p> <p>Given the large membership of the Advertising Council, it will be supported by a management sub-committee which will more regularly monitor regulatory activities associated with the advertising of therapeutic products.</p>	<p>None</p>	<p>The ASA is responsible for:</p> <ul style="list-style-type: none"> - setting and maintaining appropriate and proper standards for advertising; and - establishing and promoting an effective self regulatory system for advertising standards
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<p>Strategy and policy</p>	<p>Advertising requirements are set out in the <i>Therapeutic Goods Act 1989</i> and Regulations. The TGA is responsible for recommending to the Minister for Health any proposed changes to regulatory policy on advertising and legislative changes needed to implement them. The TGA generally consults with the Therapeutic Goods Code Council (as an advisory committee) on these proposed changes.</p>	<p>The Joint Agency will be responsible for recommending to the Ministerial Council any proposed changes to regulatory policy on advertising and legislative changes needed to implement them. The Joint Agency would generally consult with the Advertising Council (as an expert advisory committee) on these proposed changes.</p>	<p>None</p>	<p>While advertising requirements are set out in the <i>Medicines Act 1981</i> there is generally no need for legal action to be taken to achieve compliance. As these requirements are consistent with the Code for Therapeutic Advertising, compliance is brought about on a voluntary basis through the self regulatory system for advertising.</p>
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<p>Pre-approval of advertisement</p>	<p>Advertisements for medicines printed/broadcast in “specified media” (which includes printed/broadcast mainstream media) which are directed to consumers (which currently excludes the internet) require approval as a legislated requirement.</p> <p>The industry associations (ASMI and CHC) have been given legal delegations for approving advertisements and have contracts with TGA to employ Advertising Service Managers to undertake the approvals function. ASMI approves advertisements</p>	<ul style="list-style-type: none"> ▪ A ‘dividing line’ would be determined between medicines that require pre-approval and those that don’t (based on the media in which the advertisement is published or broadcast). ▪ The authority to require pre-approval of advertisements published in mainstream media (excluding the internet) would be established in Legislation and the detailed Code. ▪ For approved advertisements the approval number must be displayed on advertising. ▪ Delegation to be given to approve minor revisions of approved advertisements to be given to trained and accredited authorities. ▪ Other entities could be delegated the ability to pre-approve “first-time advertisements” in time. <p style="text-align: center;">Australia specific New Zealand specific</p>	<p>The IAC model included a requirement that advertisements for therapeutic products that do not require pre-approval would have to be notified to a Joint Agency register and subject to audit for compliance.</p> <p>The Interim Ministerial did not accept the recommendation for a notification database but agreed that advertising which did not require approval should be actively monitored for compliance with the Advertising Code and the level of compliance formally reviewed within 3 years after the implementation of the new regulatory model. If this review does not demonstrate an improved level of compliance then further regulatory measures to raise compliance are to be implemented.</p>	<p>Undertaken voluntarily in New Zealand by industry with advertising media agreeing not to publish advertisements that are not pre-approved.</p> <p>Process of approval is undertaken through the Therapeutic Advertising Pre-vetting scheme (as established by the Association of New Zealand Advertisers).</p>
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	<p>for all broadcast advertisements, and for print media for OTC medications. CHC approves print media advertisements for complementary medicines.</p>	<ul style="list-style-type: none"> ▪ Central approvals officers would be established under contract with the CHC, ASMI and MIAA and these associations would have delegation to approve advertisements. ▪ DTCA to continue to be prohibited. 	<ul style="list-style-type: none"> ▪ TAPS would continue to pre-approve advertisements. However, delegation would come from the Joint Agency. ▪ DTCA would continue to be catered for 	
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<p>Post-market monitoring</p>	<p>No formal framework for monitoring and evaluation on the effectiveness of the current advertising model is in place.</p>	<ul style="list-style-type: none"> ▪ Audits to be conducted on a random selection of advertisements on the database for pre-approved advertisements. ▪ A systemic framework for data collection and monitoring is proposed. ▪ The Advertising Council is to review reports generated as part of the proposed framework and provide feedback to the Joint Agency and an annual report to the Ministerial Council (through the Joint Agency). 		<p>Although a notification system will not be in place, audits are also to be conducted on advertising which does not require pre-approval.</p>	<p>No formal framework for monitoring and evaluation on the effectiveness of the current advertising model is in place.</p>
<p>Complaints</p>	<p>Three entry points for complaint handling include:</p> <ul style="list-style-type: none"> • Complaints Resolution Panel – (advertisements in mainstream media directed to consumers); • CHC and ASMI self-regulatory complaint panels (advertisements in non-mainstream 	<p>Australia Members of the complaints panel would be appointed by the Ministerial Council. All complaints would be made to the Central Support Unit who would triage them into: - Consumer</p>	<p>New Zealand Members of the complaints panel would be appointed by the Ministerial Council. Complaints will be dealt with by the Central Complaint Panel in New</p>	<p>The IAC model referred specifically to the Advertising Standards Complaints Board (ASCB) acting as the Central Complaints Panel in New Zealand. The model approved by the Interim Ministerial Council provides for the Managing Director to take into consideration the membership of the ASCB, when recommending to the Ministerial Council a panel of experts from which the Central Complaints Panels in Australia and New Zealand</p>	<p>Made largely by consumers to the Advertising Standards Authority, although complaints may also be submitted to the relevant industry association. The ASA is responsible for establishing an Advertising Standards Complaints Board. The ASA is bound by the Board's decisions. Some complaints are made to Medsafe and these are generally passed to the ASA for consideration.</p>

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	<p>media directed to consumers and complaints about advertisements directed to healthcare practitioners) and</p> <ul style="list-style-type: none"> • TGA (advertisements for prescription medicines directed to consumers). 	<p>complaints to be dealt with by the Central Complaints Panel (with membership from the regulator and industry)</p> <p>- Complaints about advertising to healthcare practitioners which would be dealt with by industry bodies through self-regulation.</p>	<p>Zealand. Serious matters can be referred to the Joint Agency for action.</p>	<p>will be drawn.</p>	
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<p>Sanctions</p>	<p>Complaints Resolution Panel can require the withdrawal of advertising, or the publication of retractive advertising. The panel can also refer a complaint back to the TGA for a very serious breach. The TGA can then seek recourse to the courts (maximum penalty is A\$1500) Individual industry organisations can withdraw the membership of a company for failing to meet the advertising code.</p>	<p>Pre-approved advertisements</p> <ul style="list-style-type: none"> ▪ A range of administrative sanctions, civil and criminal penalties are proposed to be available. <p>Advertisements which do not require approval</p> <ul style="list-style-type: none"> ▪ Advertisers that repeatedly issue advertisements that do not meet the Code, can be ordered to have all of their advertisements approved. ▪ The ASCB and the Central Complaints Panel are to be given legal power to issue limited corrective orders to enable timely action to be taken. The Joint Agency is to have wider enforcement powers for serious breaches and may apply sanctions if necessary to maintain consistent outcomes between Australia and New Zealand for similar offences. 	<p>None</p>	<p>If a complaint is upheld then the advertiser, advertising agency and media are, in accordance with self-regulatory principles, requested to voluntarily withdraw the advertisement.</p>
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<p>Appeals</p>	<p>Appeals may be lodged with the AAT on decisions which are of direct impact on the applicant</p>	<ul style="list-style-type: none"> • Request for internal review by Joint Agency • Appeals to merits review tribunal by any party involved in the decision. 	<p>The IAC model proposed that the decisions of the Advertising Standards Complaints Appeals Board should be accepted in Australia.</p> <p>As the Ministerial Council will not appoint members of the ASCAB, decisions of the ASCAB will need to be referred back to the ASCB to be legally underpinned in Australia and New Zealand.</p>	<p>Appeals on complaint determinations may be made to the Advertising Standards Complaints Appeals Board. The ASA is bound by the Board's decisions.</p>
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Support Services	A contract is in place between TGA and ASMI to provide Secretariat support for TGACC and the Complaints Resolution Panel, support for industry education seminars and some self-monitoring activities.	A Central Support Unit is to be established to triage complaints in Australia, provide secretariat services to the Central Complaints Panel and the Advertising Council, collect data in Australia and New Zealand and report on monitoring and evaluation framework, and oversee training/ accreditation programs for delegated authorities. The ASA will continue to provide its own administrative support for the ASCB and the ASCAB. The ANZA will continue to provide funding for administrative support for the TAPS through approvals fees.	None	The Advertising Standards Authority provides funding for administrative support for the Advertising Standards Complaint and Appeals Boards through a levy on advertisers. The Association of New Zealand Advertisers provides funding for administrative support for the TAPS through approvals fees.
Implementation Steering Group	Not applicable	A small steering group is to be established to guide the implementation work program to prepare for the commencement of the new regulatory model. Membership of the group is to include representatives of the therapeutic products, advertising, media industries, consumers, prescribers and dispensers in Australia and New Zealand.	The IAC model proposed that membership of the steering group reflect that of the management sub-committee of the Advertising Council. This membership has been expanded by the Interim Ministerial Council to include prescribers and dispensers.	Not applicable