Review of Medicines and Medical Devices Regulation – Stage Two

Report on the regulatory frameworks for complementary medicines and advertising of therapeutic goods

Emeritus Professor Lloyd Sansom AO
Mr Will Delaat AM
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July 2015
Expert Panel
Review of Medicines and Medical Devices Regulation

Report to the Minister for Health on the Regulatory Frameworks for Complementary Medicines and the Advertising of Therapeutic Goods

31 July 2015

Emeritus Professor Lloyd Sansom AO
Mr Will Delaat AM
Professor John Horvath AO
The Hon Sussan Ley MP  
Minister for Health  
Parliament House  
CANBERRA ACT 2600

Dear Minister Ley

The Independent Panel for the Review of Medicines and Medical Devices Regulation is pleased to present its Report on the second stage of the Review. The Report for stage one, which examined the regulation of medicines and medical devices, was presented to you on 31 March 2015.

In accordance with the Review’s Terms of Reference, the Report on stage two examines and makes high level recommendations on the regulatory frameworks for complementary medicines, and for the advertising of therapeutic goods. The Report makes a further twenty six recommendations to the stage one Report. In line with the Government’s Industry, Innovation and Competitiveness Agenda, a number of recommendations propose enhancements to the regulatory frameworks to better align protections with risks, and to ease regulatory requirements where they do little to improve consumer protections and are a barrier to business and innovation. The recommendations also aim to increase the information available to consumers to support their health decisions, and to improve the transparency of regulatory processes for all stakeholders.

In developing the Report, the Panel has been cognisant of the growing trend toward self-medication and the increasing use of complementary medicines by consumers to actively protect and manage their own health. This is predicated on the assumption that all therapeutic products on the Australian market have been assessed for safety, quality and efficacy. Further, the regulatory framework underpins the reputation of Australian companies for producing high quality products and their domestic and international competitiveness in burgeoning overseas markets. The Panel was also mindful that accurate information in advertising about the uses and efficacy of these products is a critical element in consumer decision-making with consequences for health outcomes, and is also a factor in the reputation of Australian companies.

In undertaking the Review, the Panel sought comment from stakeholders on the regulatory framework for complementary medicines, receiving forty seven submissions from consumers, industry and health professionals. The Panel also considered stage one submissions that addressed the regulatory framework for the advertising of therapeutic goods. In addition, a number of face-to-face and teleconference consultations were held with stakeholders from April to mid-June 2015.

The Panel is pleased to present the culmination of both stages of the Review.

Yours sincerely

Emeritus Professor Lloyd Sansom AO  
Chair  
Prof John Horvath AO  
Mr Will Delaat AM

31 July 2015

cc: The Hon Tony Abbott MP, Prime Minister  
The Hon Christian Porter MP, Parliamentary Secretary to the Prime Minister  
Senator the Hon Fiona Nash, Assistant Minister for Health
ACKNOWLEDGEMENTS

The Panel would like to acknowledge the following people and organisations for their contribution throughout this process:

Therapeutic Goods Administration

The Panel would like to thank Adjunct Professor John Skerritt and the staff of the TGA for their openness in engaging with the Panel and for their timely responses to the Panel’s many requests for information.

Secretariat Services

The Panel wishes to acknowledge the support that it received from the secretariat in the management of the Review and in preparation of the Review Report:

Department of Health - Ms Cheryl Wilson, Ms Michelle Palombi, Ms Teressa Ward, Mr Thomas Ashby, Ms Fran Verass, Ms Julie Dennett, Mr Jonathan Ayre, Ms Krystyna Turnsek and Ms Danielle Dalton.

Stakeholders

The Panel would also like to thank all the stakeholders and individuals who provided submissions for the Review, and to all those who attended the consultation forums.
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RECOMMENDATIONS

RECOMMENDATIONS RELATING TO THE COMPLEMENTARY MEDICINES REGULATORY FRAMEWORK

Recommendation Thirty Three
The Panel recommends that listed medicinal products, including complementary medicinal products, and the ingredients for use in such products, continue to be regulated within the therapeutic goods framework.

Recommendation Thirty Four
The Panel recommends that the redrafted *Therapeutic Goods Act 1989* is amended to provide the NRA with the capacity to refuse to list in the ARTG complementary medicinal products and other listed medicinal products that have the potential to undermine Australia’s public health efforts.

Recommendation Thirty Five
The Panel recommends that the NRA continues to evaluate ingredients for use in listed medicinal products, and requires listed medicinal products to only include ingredients that have been approved for use in listed products. In undertaking an evaluation of ingredients the NRA should continue to give consideration to:

A. the safety of the proposed ingredient, taking into account factors such as: proposed dosage; route of administration; frequency and duration of administration; and possible drug interactions;

B. working with stakeholders to identify a broader range of appropriate sources of evidence for the quality of new ingredients, which may change over time; and

C. the quality of the proposed ingredients, including proposed methodology for ensuring product purity, consistency, stability and other aspects of the PIC/S GMP.

Recommendation Thirty Six
The Panel recommends that a sponsor seeking to have a new ingredient assessed by the NRA for use in listed medicinal products, including complementary medicinal products, is able to either:

A. submit data relating to the safety and quality of the proposed ingredient for use in listed medicinal products for de novo assessment by the NRA; or

B. submit an un-redacted evaluation report from a comparable overseas NRA, along with a copy of the dossier submitted to that NRA and data supporting specific Australian requirements, such as labelling, to the Australian NRA for assessment (refer to Recommendation Five). The Australian NRA to make a recommendation regarding use of the ingredient in listed medicinal products once it has considered the data within the Australian context.
**Recommendation Thirty Seven**
The Panel recommends that the NRA develop and maintain, in real time, a catalogue of approved ingredients for use in listed medicinal products that is readily accessible to sponsors and the general public.

**Recommendation Thirty Eight**
The Panel recommends that the NRA establishes the list of Permitted Indications, from which sponsors must exclusively draw, for listed medicinal products in the ARTG.

**Recommendation Thirty Nine**
The Panel recommends that there be three options by which sponsors may seek entry into the ARTG of complementary medicinal products and other listed medicinal products for supply in Australia.

**Option One**
Listing in the ARTG following self-declaration by the sponsor of the safety and quality of the product in circumstances where:

A. the product contains only ingredients that have been previously approved by the NRA for inclusion in listed medicinal products; and

B. the ingredients, including proposed dosage where applicable, route of administration, and duration of use where applicable, comply with listing notices or similar documents issued or endorsed by the NRA; and

C. the ingredients comply with any compositional guidelines or other compendial standards issued, adopted or approved by the NRA; and

D. the product is manufactured in accordance with PIC/S GMP; and

E. the sponsor only seeks to make claims regarding the indications for use of the product selected from the list of Permitted Indications (Recommendation Thirty Eight refers); and

F. the sponsor holds evidence to support these indications, consistent with requirements outlined in the evidence guidelines issued by the NRA from time to time.
Option Two

Listing in the ARTG following a self-assessment of the safety and quality of the product, and following assessment of the efficacy of the product by the NRA, in circumstances where:

A. the product contains only ingredients that have been previously approved by the NRA for inclusion in listed medicinal products; and

B. the ingredients, including proposed dosage where applicable, route of administration, and duration of use where applicable, are compliant with listing notices or similar documents issued or endorsed by the NRA; and

C. the ingredients comply with any compositional guidelines or other compendial standards issued, adopted or approved by the NRA; and

D. the product is manufactured in accordance with PIC/S GMP; and

E. the sponsor seeks to make health claims that fall outside the list of Permitted Indications but which are still appropriate for listed medicinal products; and

F. the sponsor can provide evidence acceptable to the NRA to support the safety and efficacy of the product for the proposed indication(s), commensurate with risk. This may include the submission of an un-redacted evaluation report(s) from a comparable overseas regulator.

Option Three

Registration of a complementary medicinal product in the ARTG following an assessment by the NRA of the product for safety, quality and efficacy in accordance with existing requirements for registration of complementary medicines (Recommendation Forty refers).

Recommendation Forty

The Panel recommends that where a sponsor seeks to include a complementary medicinal product in the ARTG that the sponsor is able to do so utilising registration Pathways One or Two, namely:

Pathway One

Submission of a complete dossier for de novo assessment. This assessment may be undertaken in full by the Australian NRA or via a work-sharing arrangement between the Australian NRA and a comparable overseas NRA.

Pathway Two

Submission of an un-redacted evaluation report from a comparable overseas NRA, along with a copy of the dossier submitted to the comparable overseas NRA and Australian specific data similar to that provided by sponsors in Module 1 of the Common Technical Document, for assessment by the Australian NRA. The Australian NRA to make a recommendation regarding registration of the complementary medicinal product once it has considered the data within the Australian context.
Recommendation Forty One
The Panel recommends that the NRA develops, in consultation with industry, legislative timeframes for the:

A. assessment of new ingredients for use in listed medicinal products;
B. publication of finalised compositional guidelines for newly approved ingredients for use in listed medicinal products, where appropriate;
C. assessment of medicinal products listed under Option Two; and
D. registration of medicinal products under Option Three.

Recommendation Forty Two
The Panel recommends that, consistent with Recommendation Thirteen, the NRA adopt a risk-based approach to the management of variations to complementary medicines listed in the ARTG. This approach should provide for:

A. notification of variations to the NRA in circumstances where the variation does not impact the quality, safety or efficacy of the product; or
B. assessment of the variation by the NRA in circumstances where the variation has the potential to impact the safety, quality or efficacy of the medicine. This assessment to be abridged in scope, so that only those aspects that require evaluation in order to establish the continued safety, quality and efficacy of the complementary medicine following implementation of the proposed variation are examined (abridged assessment).

Recommendation Forty Three
The Panel recommends that where a medicinal product is listed in the ARTG, the sponsor be required to publish on the sponsor’s website or, if the sponsor does not have a website, on another website nominated by the NRA, the evidence that it holds to support all indications included in the ARTG entry.

Recommendation Forty Four
The Panel recommends that where a medicinal product is listed in the ARTG under Option One (self-assessment), the sponsor is required to include a prominent disclaimer on all promotional materials relating to the product, including product information on websites, to the effect that the efficacy claims for the product have not been independently assessed and/or are based on traditional use.

Recommendation Forty Five
The Panel recommends that where a medicinal product is listed in the ARTG following an assessment by the NRA of an application under Option Two, the sponsor is able to indicate on all promotional materials and on the product label, that the efficacy of the product has been independently assessed for the approved indication(s).
**Recommendation Forty Six**
The Panel recommends that the NRA develops or adopts from comparable overseas regulators, efficacy monographs for commonly used active ingredients that have been approved for use in listed medicinal products. Such monographs would document the evidence supporting the efficacy of the ingredients for specific indications and other relevant information.

**Recommendation Forty Seven**
The Panel recommends that, in revising the *Therapeutic Goods Act 1989* and subordinate legislation (Recommendation Twenty Eight refers), the Australian Government provides review and appeal rights for the sponsor who has lodged an application for a new ingredient (to be approved for a listed medicine) to seek a review of an NRA decision regarding that application.

**Recommendation Forty Eight**
The Panel recommends that the Australian Government undertakes a review of the range of complementary medicinal products, currently listed in the ARTG and subject to regulation under the medicines framework, with a view to ensuring that products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act.

**Recommendation Forty Nine**
The Panel recommends that the NRA develops a more comprehensive post-market monitoring scheme for listed medicinal products, including complementary medicinal products. Such a scheme should include:

A. an increase in the number of products subject to random/targeted post-market review;
B. provisions to allow the NRA to complete a post-market review in the event that the sponsor withdraws the product from the ARTG during the course of the review;
C. timely availability of information for consumers for each listed product in relation to whether the product has been subject to post-market review, and the timing and outcome of any review;
D. integration and timely analysis of any available datasets, including eHealth and hospital records, to provide a more streamlined and cost-effective approach to post-market monitoring (Recommendation Twenty Seven refers), particularly of products including newly approved ingredients;
E. provision for electronic reporting of adverse events; and
F. enhanced collaboration with overseas NRAs to share information relating to safety or efficacy of comparable products.
Recommendation Fifty
The Panel recommends that the Australian Government gives consideration to improving the competitiveness of the Australian complementary medicines industry by providing incentives for innovation.

Recommendation Fifty One
The Panel recommends that the statutory Advisory Committee on Complementary Medicines is retained, and that the committee:

A. is composed of a range of experts across relevant fields and consumer representation, as required over time;

B. at the request of the NRA, provides advice regarding the inclusion, variation, removal of complementary medicinal products from the ARTG and any other matters relating to complementary medicines; and

C. takes into account any other information that the committee considers is material to its deliberations.
RECOMMENDATIONS RELATING TO THE THERAPEUTIC GOODS ADVERTISING FRAMEWORK

Recommendation Fifty Two
The Panel recommends that advertising of therapeutic products to the public continues to be regulated by the NRA under a legislative framework which includes an advertising code.

Recommendation Fifty Three
The Panel recommends that advertising to the public continues to be prohibited for Schedule 4 and 8 prescription medicines, and the advertising of medicines in Schedule 3 of the *Poisons Standard* continues to be prohibited except those products containing ingredients set out in Appendix H (Recommendation Twelve refers).

Recommendation Fifty Four
The Panel recommends that the future requirements for advertising therapeutic products to the public are made consistent for all medicines and medical devices.

Recommendation Fifty Five
The Panel recommends that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime.

Recommendation Fifty Six
The Panel recommends that current mechanisms for managing complaints are disbanded and a new mechanism is established consistent with best practice principles for complaint handling. In establishing the new complaints management mechanism, a single agency should be responsible to receive and manage complaints on the advertising of therapeutic products to the public. The Government should consider the following options:

A. establishing the function within the NRA or other existing Commonwealth agency and ensuring appropriate resourcing for the function; or

B. calling for tenders from external organisations to undertake the function.

Recommendation Fifty Seven
The Panel recommends that, further to Recommendation Twenty Eight regarding a review of the Act, consideration be given as to whether the current range of investigation and enforcement powers should be broadened.

Recommendation Fifty Eight
The Panel recommends that the NRA facilitates the development of a formal sponsor education programme to provide industry and industry associations with appropriate information and tools to assist them in achieving compliance with advertising requirements under the regulatory framework.
# GLOSSARY OF ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACCC</td>
<td>Australian Competition and Consumer Commission</td>
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<tr>
<td>ACCM</td>
<td>Advisory Committee on Complementary Medicines</td>
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<tr>
<td>ANAO</td>
<td>Australian National Audit Office</td>
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<tr>
<td>ARTG</td>
<td>Australian Register of Therapeutic Goods</td>
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<tr>
<td>ASB</td>
<td>Advertising Standards Bureau</td>
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<tr>
<td>ASMI</td>
<td>Australian Self Medication Industry</td>
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<tr>
<td>AusPAR</td>
<td>Australian Public Assessment Report</td>
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<tr>
<td>CMA</td>
<td>Complementary Medicines Australia</td>
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<tr>
<td>CHC</td>
<td>Complementary Healthcare Council of Australia</td>
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<tr>
<td>CRP</td>
<td>Complaints Resolution Panel</td>
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<tr>
<td>CTD</td>
<td>Common Technical Document</td>
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<tr>
<td>CMI</td>
<td>Consumer Medicines Information</td>
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<tr>
<td>ELF</td>
<td>TGA eBusiness Services Electronic Listing Facility</td>
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<tr>
<td>EMA</td>
<td>European Medicines Agency</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration (US)</td>
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<tr>
<td>FTC</td>
<td>Federal Trade Commission (US)</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>MHRA</td>
<td>Medicines and Healthcare products Regulatory Agency (UK)</td>
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<tr>
<td>MTAA</td>
<td>Medical Technology Association of Australia</td>
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<tr>
<td>NNHPD</td>
<td>Natural and Non-prescription Health Products Directorate</td>
</tr>
<tr>
<td>NRA</td>
<td>National Regulatory Authority – currently the TGA in Australia</td>
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<tr>
<td>OTC</td>
<td>Over-the-counter</td>
</tr>
<tr>
<td>PAGB</td>
<td>Proprietary Association of Great Britain</td>
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**Glossary of Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>PI</td>
<td>Product Information</td>
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<tr>
<td>PIC/S</td>
<td>Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme</td>
</tr>
<tr>
<td>RIS</td>
<td>Regulation Impact Statement</td>
</tr>
<tr>
<td>TAPS</td>
<td>Therapeutic Advertising Pre-vetting Service</td>
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<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<tr>
<td>TGACC</td>
<td>Therapeutic Goods Advertising Code Council</td>
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<tr>
<td>TIWGG</td>
<td>TGA-Industry Working Group on GMP</td>
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<tr>
<td>UK</td>
<td>United Kingdom</td>
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<td>US</td>
<td>United States</td>
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<td>WHO</td>
<td>World Health Organization</td>
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CHAPTER EIGHT: BACKGROUND AND CONTEXT

This document is the second report of the independent Review of Medicines and Medical Devices Regulation (the Review), announced on 24 October 2014 by the then Minister for Health, the Hon Peter Dutton MP and the Assistant Minister for Health, Senator the Hon Fiona Nash.

The Review has been undertaken by an Expert Panel, in two stages:

- **stage one** of the Review focused on the regulation of prescription medicines, over-the-counter (OTC) medicines, medical devices and access to unapproved therapeutic goods. The first report covering stage one was provided to the Minister for Health on 31 March 2015 and was publicly released by the Government on 24 June 2015; and

- **stage two** focuses on the regulatory framework for both complementary medicines and the advertising of therapeutic goods. While the Panel sought comment from stakeholders on the advertising of medicines and medical devices as part of stage one of the Review, it did not consider it appropriate to make recommendations on this issue until it had also considered advertising in the context of complementary medicines, in order to capture all classes of therapeutic goods.

This second report covers stage two of the Review and has been written in accordance with the Terms of Reference. The Terms of Reference and details about the Expert Panel are set out in Chapter One, pages 1 to 4.

8.1 Review methodology, themes, principles and discussion papers

The Review methodology, themes, principles and approach to discussion papers and consultations remain consistent for the first and second reports. Refer to Chapter One, pages 4 to 6.

The first discussion paper, released on 21 November 2014, addressed the framework for advertising therapeutic goods (among other matters). A second discussion paper was released on 20 February 2015 and addressed issues relating to the regulation of complementary medicines.

Both discussion papers were published on the Department of Health’s website and were accompanied by a call for submissions inviting stakeholders to provide input to the Review. The call for submissions was also emailed to a broad range of consumer, industry and health professional peak bodies, as well as to organisations or individuals who had registered an interest in the Review. Submissions responding to the second discussion paper closed on 8 April 2015, although late submissions were still considered.
8.2 Submissions

In response to the *Review of Medicines and Medical Devices Regulation Discussion Paper – Chapter Nine: Regulation of Complementary Medicines*, the Panel received 47 formal submissions from a range of stakeholders (see Appendix A). As outlined in Figure 15 below, submissions were received from:

- industry, including submissions from both individual companies and peak bodies representing the interests of industry;
- health professionals, including both individuals and representative bodies;
- consumer peak bodies and individual consumers;
- academics; and
- other groups, such as regulatory consultants.

Figure 15: Submissions received in response to the Panel’s second discussion paper on Medicines and Medical Devices Regulation

The Panel reviewed all submissions. Where submissions raised issues that the Panel wished to further explore or clarify, the Panel sought a meeting with the relevant party. Where possible, all Panel members were present at such meetings, but on occasion meetings were held with the Chair only, or with two members of the Panel.

Where consent was provided by the author, submissions received were published on the Department of Health’s website.
8.3 Consultations

As noted above, the Panel met with a range of stakeholders to discuss their submissions or seek clarification on issues raised. A list of organisations external to the Department of Health with whom the Panel consulted is at Appendix B. Throughout the Review, the Panel also regularly sought information and advice from the Therapeutic Goods Administration (TGA) or from other relevant officers within the Department of Health.

8.4 National Regulatory Authority

The authority responsible for regulating therapeutic goods in Australia is the TGA, which is part of the Australian Government Department of Health. The TGA is responsible for regulating a diverse range of therapeutic products, including prescription and non-prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products. The regulatory framework under which the TGA operates is set out in the Therapeutic Goods Act 1989 (the Act) and related Regulations.

Throughout this report, when discussing past actions of the authority, the Panel has referred to the TGA. However, to be consistent with the nomenclature used by the World Health Organization, when referring to the Australian regulatory authority in general terms or in future tense, the Panel has used the term ‘National Regulatory Authority’ (NRA).

8.5 TGA performance

While submissions to stage two of the Review have reiterated that the TGA is respected internationally and domestically as a regulator of therapeutic goods, the TGA has nonetheless been subject to some criticisms from:

- industry about the regulatory burden associated with providing information to support the listing of low-risk medicines on the Australian Register of Therapeutic Goods (ARTG); seeking pre-approval of advertising; the complexities of the complaints resolution scheme; as well as about a lack of incentives for innovation in the complementary medicines sector; and

- consumers and health professionals about a lack of clear information on labels and advertising that the efficacy of listed medicines is not independently assessed by the regulator; the complexity in lodging complaints and lack of timeliness and transparency in the administration of complaints; and the inadequacy of enforcement efforts in regard to breaches.

These matters will be discussed in more detail in Chapters Nine and Ten.

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1 Note: The regulation of blood and blood products is not included in the terms of reference for this Review.
8.6 Complementary medicines

In Australia, complementary medicinal products generally refer to vitamins, minerals and nutritional supplements, herbal and homeopathic medicines, and aromatherapy products for which therapeutic claims are made.¹ There are over 12,000 complementary medicines available on the Australian market. The vast majority are in the lower risk listed category with only about 140 products in the higher risk registered category.² The definition of complementary medicines under the Act is set out in Chapter Nine, Section 9.1. These products may be recommended for use by a range of parties including naturopaths, acupuncturists, traditional medicine practitioners, health food store workers,³ medical practitioners and pharmacists.⁴

8.6.1 Use

The use of complementary medicines has increased rapidly in Australia, as it has in other western countries, over the last two decades.⁵ A National Prescribing Services report noted that in 1993 about 48.5 per cent of the population (in a South Australian survey) used complementary medicines, while a 2006 national survey showed that about 67 per cent of the population, or two out of three people in Australia, used complementary medicines.⁶

Consumers are purchasing complementary medicines from a range of sources including pharmacies (51 per cent), supermarkets (33 per cent) and health food shops (31 per cent), and directly from their treating complementary medicine practitioners (<10 per cent).⁷

The use of complementary medicines in Australia is largely motivated by consumers’ desire to actively maintain their own health, or to treat, or address the side effects of conventional treatments for chronic diseases.⁸ Many users, however, have inadequate information about the complementary medicinal products they use. A 2008 survey of complementary medicine users found that while many users were taking complementary medicines for conditions where there is some evidence, many reported using complementary medicines for reasons where there is no evidence, or where they were uncertain about the reasons for their use.⁹

Consumers seek information on complementary medicines from multiple sources: predominantly family, friends and the Internet (>50 per cent); followed by retailers (>37 per cent), general practitioners (>33 per cent), package inserts/labels/pamphlets and a range of complementary therapists (about 30 per cent). However consumers were more inclined to seek information on the benefits as opposed to the risks.¹⁰ That may be explained in part by a significant proportion of consumers believing that complementary medicines are natural products and as such are safer than conventional pharmaceuticals or free of risk.¹¹ A third of surveyed consumers did not know that the efficacy of most complementary medicines is not independently verified by the national regulator. About half of all consumers who use complementary medicines and conventional medicines concurrently do not report their use of complementary medicines to their doctor.¹²
The Panel recognises that complementary medicines generally have a history of traditional use and, if manufactured in line with the principles of good manufacturing practice, are generally of lower risk and that regulations should be commensurate with that lower risk. However, they are not risk free, and there is a high community expectation in Australia that government has a role in protecting public health.

8.6.2 Complementary medicines sector

The World Health Organization has noted that not only is there increasing worldwide use by consumers of complementary medicines, but that the complementary medicines sector is a global industry of growing importance to national economies.\textsuperscript{13}

There are about 3,000 sponsors of complementary medicines in Australia, including both listed and registered medicines. The sponsor is generally the manufacturer, importer or exporter of the medicine.\textsuperscript{14}

In 2012-13, the pharmaceutical industry in Australia had $23.4 billion in turnover, with exports of $3.89 billion. It directly employed about 41,000 people of which nearly 15,500 were in manufacturing.\textsuperscript{15} Within that broader context, industry-commissioned research by the complementary medicines sector shows that revenue from complementary medicines is between $2 billion\textsuperscript{16} and $3.5 billion per annum,\textsuperscript{17} with about 5,000 people being employed in high skilled manufacturing positions\textsuperscript{18} and with a further 40,000 to 60,000 people indirectly employed. Revenue is expected to grow to about $4.6 billion in 2017-2018. Exports to more than 20 countries in Southeast Asia, Europe and the Americas are greater than $200 million.\textsuperscript{19}

8.6.3. Aims of this Report

Given the increasing consumer use of complementary medicines, the inherent risk in the administration of any medicine and the involvement of a wide range of practitioners and health professionals in prescribing complementary medicines for consumers, governments all over the world are developing or refining strategies to better manage integrated health care.\textsuperscript{20} The Panel is cognisant that in doing so, the Australian Government is seeking to balance supporting consumers' choices and access to these medicines, with their safe and effective use. The World Health Organization recommends that these objectives be facilitated through support for improving the evidence base and an appropriate level of regulation.\textsuperscript{21}

With unprecedented growth in the economies of China, India, Indonesia, Vietnam, Malaysia and the Philippines,\textsuperscript{22} consumption of complementary medicines is growing faster in these export markets than they are domestically.\textsuperscript{23} As such, the Panel is conscious that the report recommendations align with Australia's\textsuperscript{\textit{Industry Innovation and Competitiveness Agenda}} to support this sector to develop, innovate and maintain its competitiveness in the global context.
market. The Agenda indicates that ‘a lower cost, business friendly environment with less regulation’ is critical to achieving this outcome.  

The Panel is also aware that the high domestic and international demand for Australian therapeutic products is based on consumers’ recognition that Australian regulation underpins a high quality, safe product. The report recommendations are consistent with the aims of the Industry Innovation and Competitiveness Agenda, to ‘build on Australia’s strengths not prop up under performers’ and achieve a careful balance between ‘ensuring that government responses are measured and effective, while minimising adverse side-effects and business uncertainty’. This is important to industry as well as consumers.

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6 Ibid.

7 Ibid., p. 25.


11 Ibid., p.6.

12 Ibid.

13 WHO, op. cit., p. 18.


18 Complementary Health Care Council of Australia (2013, October), op. cit.
19 Ibid.
21 Ibid., p. 8.
25 Ibid.
CHAPTER NINE: REGULATORY FRAMEWORK FOR COMPLEMENTARY MEDICINES

The Therapeutic Goods Act 1989 (the Act) and associated delegated legislation sets out the key elements of Australia’s regulatory scheme for therapeutic goods. The Act provides for a national system of controls relating to the quality, safety, efficacy, performance and timely availability of therapeutic goods used in Australia or exported from Australia. These controls are risk-based. That is, the amount and nature of regulatory control exerted by the Therapeutic Goods Administration (TGA) varies depending on the level of risk that a product poses to the Australian public. In determining risk, the TGA takes into account a range of factors, including the inherent properties of the therapeutic product; the way in which the product is designed to be used; potential for misuse; the potential severity and consequences of adverse events; and the quality of the product.

The regulatory framework divides products into low-risk and higher risk medicines. The regulation of higher risk medicines was discussed in the Panel’s first report. Medicines considered to be of higher risk, including all prescription medicines, must be registered in the Australian Register of Therapeutic Goods (ARTG) before being marketed in Australia. For a medicine to be registered, the product sponsor must submit data to the TGA which establishes the quality, safety, and efficacy of the medicine for the proposed indications. The TGA comprehensively evaluates the data. If it concludes that the benefits of the medicine outweigh the risks, the TGA will register the product in the ARTG. Registered complementary medicines are able to make claims consistent with the approved indications for use in the ARTG entry, and are assigned a unique AUST R number, which must be displayed on the medicine label. As at 31 December 2014, a small number of complementary medicines (n=141) were registered in the ARTG.

In contrast, low-risk medicines are listed in the ARTG by the product sponsor without any TGA assessment. The sponsor undertakes a self-assessment and declares that the product meets the requirements for a listed medicine under section 26A (2) (a)-(k) and, if applicable, subsection 26A (3) of the Act (which relates to overseas manufacture). As at 31 December 2014, 12,301 products were listed in the ARTG, the vast majority of which are complementary medicines.

9.1 Complementary medicines

The Therapeutic Goods Regulations 1990 (the Regulations) define a complementary medicine as

‘a therapeutic good consisting wholly or principally of 1 or more designated active ingredients, each of which has a clearly established identity and a traditional use.’
For a complementary medicine to be listed in the ARTG it:

- may only contain low-risk (active and excipient) ingredients approved by the TGA for use in listed medicines;
- may only claim indications permitted for use in listed medicines;
- must not be a prohibited import for the purposes of the *Customs Act 1901*;
- must not be required to be sterile; and
- must comply with all legislative requirements in relation to quality, safety and efficacy.\(^3\)

A designated active ingredient for a complementary medicine means *an active ingredient, or a kind of active ingredient, mentioned in Schedule 14 of the Regulations*, as named in Table 8.

**Table 8: Designated active ingredients for use in listed complementary medicinal products**

<table>
<thead>
<tr>
<th>Designated Ingredients</th>
</tr>
</thead>
<tbody>
<tr>
<td>an amino acid</td>
</tr>
<tr>
<td>charcoal</td>
</tr>
<tr>
<td>a choline salt</td>
</tr>
<tr>
<td>an essential oil</td>
</tr>
<tr>
<td>plant or herbal material (or a synthetically produced substitute), including plant fibre, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll</td>
</tr>
<tr>
<td>a homeopathic preparation</td>
</tr>
<tr>
<td>a microorganism, whole or extracted, except a vaccine</td>
</tr>
<tr>
<td>a mineral including a mineral salt and a naturally occurring mineral</td>
</tr>
<tr>
<td>a mucopolysaccharide</td>
</tr>
<tr>
<td>non-human animal material (or a synthetically produced substitute) including dried material, bone and cartilage, fats and oils and other extracts or concentrates</td>
</tr>
<tr>
<td>a lipid, including an essential fatty acid or phospholipid</td>
</tr>
<tr>
<td>a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis</td>
</tr>
<tr>
<td>a sugar, polysaccharide or carbohydrate</td>
</tr>
<tr>
<td>a vitamin or pro-vitamin</td>
</tr>
</tbody>
</table>
9.2 Current regulatory framework for complementary medicines

While the vast majority of products listed in the ARTG are complementary medicinal products, the Act does not provide a regulatory framework that is specific to these goods. Rather, as noted above, it divides all medicinal products, regardless of whether or not they meet the definition of a complementary medicine, into two categories; those that must be registered in the ARTG following TGA evaluation; and those that are considered to be of sufficiently low risk to be listed in the ARTG on the basis of a sponsor’s conformity declaration.

9.2.1 Listed medicines, including complementary medicines

Listed medicines are generally self-selected by a consumer and used for self-treatment. For a medicinal product to be listed in the ARTG, it must:

- only contain certain approved low-risk ingredients in acceptable amounts and for particular roles (e.g. active, excipient and/or component);
- be manufactured in accordance with the principles of Good Manufacturing Practice (GMP); and
- only make claims for therapeutic use for health maintenance and health enhancement or certain indications for non-serious, self-limiting conditions.\(^4\)

9.2.1.1 Approval of ingredients

As noted above, listed medicinal products can only contain ingredients that have been approved by the TGA. This includes both pharmacologically active ingredients and excipients, such as diluents or fillers, binders, colouring agents and preservatives. The vast majority of ingredients authorised for use in listed medicinal products were ‘grandfathered’ at the time that the scheme began based on their history of safe use within Australia. For a new ingredient to be added to the list of permitted ingredients, it must be evaluated by the TGA.

Substances of the types listed as ‘designated active ingredients’ in Schedule 14 of the Regulations (Section 9.1 Table 8 refers) may be eligible to be evaluated for use as an active ingredient in listed medicinal products providing that:

- the substance is not a prohibited import;
- the origin of the substance is not from a herb that is subject to a restriction or included in the list of Plant materials from which herbal substances in listable goods must not be derived (Division 1 of Part 4 of Schedule 4 to the Regulations); and
- the substance or its constituents are not subject to the relevant conditions of a Schedule or applicable appendix to the Poisons Standard.\(^5\)
A sponsor seeking to include a new ingredient on the list of ingredients permitted in listed medicinal products must make an application to the TGA providing the necessary data to establish the safety and quality of the proposed ingredient, and pay an evaluation fee. While there is no prescribed format for applications for the approval of an ingredient, sponsors are encouraged to submit data consistent with the Common Technical Document (CTD) format adopted for applications to register a new chemical entity. The fee payable is calculated based on the total number of pages of clinical and toxicology data submitted and, as at 1 July 2014, ranges from $9,665 for ≤50 pages to $67,600 for > 3,000 pages.

Once an application is accepted, the TGA undertakes an evaluation to determine whether the new active or excipient ingredient is of sufficiently low risk. There is currently no statutory timeframe for the evaluation of ingredients for use in listed medicinal products, but stakeholders claim that an evaluation can take one to two years to complete. The TGA indicates that ‘the complexity of the ingredient, the adequacy and the quality of the data submitted in the application will all influence the length of time required for evaluation’.

The TGA examines the quality and safety of the ingredient. In terms of quality, where there is a recognised default standard for the ingredient, i.e. from the British Pharmacopoeia, United States Pharmacopoeia-National Formulary or the European Pharmacopoeia, the ingredient is assessed to ensure that it complies with all the requirements of that standard. Where no recognised default standard exists, and the ingredient is approved, a Compositional Guideline is developed which provides a summary of descriptions, tests and appropriate acceptance criteria that define the characteristics and specify the composition of the ingredient as permitted for use in listed medicines. Depending on the substance, it may include descriptions of the appearance, aroma, species name (if applicable), form, component compounds, and chemical chromatography ‘fingerprint’ of the substance. It also stipulates the maximum concentration of some impurities, such as heavy metals and pesticides.

In terms of safety, the TGA evaluation seeks to determine if the toxicological profile of the ingredient is appropriate to the purpose for which it will be used and is considered safe to be included in listed medicines. Within this context, the evaluation includes consideration of the proposed therapeutic indications for the medicinal products that will contain the proposed ingredient and assesses whether it is safe at the proposed dosage, route of administration and duration of exposure.

If the TGA is satisfied with the quality of the ingredient and determines that it is safe, it will approve the substance for use as an ingredient in listed medicines. Where the approved ingredient is an active ingredient, its approval is documented in a Therapeutic Goods Listing Notice (Listing Notice), which includes any limitations on the use of the substance. The limitations may address known interactions with drugs, or contraindications, or identify population subgroups (such as children, pregnant women or lactating mothers) that are not covered, because the safety has not been established. For example, Therapeutic Goods
(Listing) Notice 2015 (No. 1),[^1] provides for use of the ingredient ubiquinol-10 in certain listed products subject to the following conditions:

- the preparations are for oral use only; and
- the preparations provide not more than 300 mg ubiquinol-10 per daily dose; and
- when used in combination with ubidecarenone, the preparations provide not more than 300 mg of ubiquinol-10 and ubidecarenone combined per daily dose; and
- the container, and any other packaging, for the preparation is labelled with the following warning: ‘Not to be taken, if on warfarin therapy, without medical advice’.

As a legislative instrument which is tabled in Parliament, the Listing Notice takes effect on the day of tabling and sponsors are able to list products containing that ingredient in the ARTG from then, unless the Listing Notice is subsequently revoked.

### 9.2.1.2 Good Manufacturing Practice

Both registered and listed medicines, including complementary medicines, must comply with internationally accepted GMP principles developed by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S). These principles set out requirements relating to quality management, personnel, premises and equipment, documentation, production, quality control, contract manufacture and analysis, complaints and product recall and self-inspection. The observance of these requirements is necessary across all stages of manufacture, and they are applicable to the manufacture of both ingredients and of the finished complementary medicinal product. Some manufacturers are exempt from GMP license requirements, for example, manufacturers of ingredients that do not have a therapeutic action, oils extracted from herbs to be used as a starting material for use by a licensed manufacturer (e.g. lavender oil), or certain homeopathic preparations. Compliance is assessed through regular on-site inspections of manufacturer facilities.[^10] The interval between inspections for low-risk products is between 12 months and three years, and determined using a risk matrix that considers the product and process risks, and the manufacturer’s compliance history.[^11]

Unless subject to specified exemptions, medicines manufactured in Australia cannot be registered or listed in the ARTG unless each step has been carried out by a manufacturer that has been licensed by the TGA. If any (or all) of the steps in the manufacture of a medicine have been carried out overseas, listing or registering the product in the ARTG is subject to those steps being performed to the same standard expected of Australian licensed manufacturers. In order to satisfy itself, the TGA may inspect the overseas premises or, if the premises have been inspected and authorised by a comparable overseas counterpart, the TGA may accept this authorisation. The TGA has entered into several

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[^1]: The first listing notice made this year (effective 6 February 2015).
international agreements with overseas regulators for this purpose, and the vast majority (more than 90 per cent) of overseas medicine GMP applications are ‘cleared’ based on these inspections, rather than requiring the TGA to conduct an on-site inspection.

Recognising that listed and registered complementary medicines may differ from other medicines, the TGA has issued documentation providing specific guidance to industry on GMP requirements for complementary medicines. Further guidance is in the PIC/S GMP Annex 7 – Manufacture of herbal medicinal products.  

### 9.2.1.3 Indications and claims for therapeutic use

The Act defines an indication as ‘the specific therapeutic use/s of the goods.’ When a medicinal product is listed or registered in the ARTG, the entry must include the indication(s) for the product. Listed medicines are generally restricted in their indications for therapeutic use, noting that the TGA does not evaluate the efficacy of a listed product. However, the applicant must certify that they hold evidence to support indications for therapeutic use that they propose to include in the ARTG listing and that the information provided in the application is correct.

Notably, this restriction does not apply to mother tinctures and other homeopathic preparations that are required to be included in the ARTG. This means that the sponsors of such products are not limited in the indications that they may make in the ARTG entry, although it is noted that the requirement to hold evidence to support any indication still applies. The Panel considers this to be an anomaly, and considers that in redrafting the Act (Recommendation Twenty Eight refers), this issue should be addressed.

### 9.2.1.4 Self-assessment and certification for listed medicinal products

There is no independent assessment by the TGA of the sponsor’s certifications before the product is listed in the ARTG and, as such, sponsors of listed medicines can generally supply their product in Australia rapidly after submitting an electronic application. In making an application, a sponsor provides a statutory declaration self-certifying that their product meets the regulatory requirements for listing through the TGA eBusiness Services Electronic Listing Facility (ELF). The sponsor receives notification of the assigned ARTG entry, and AUST L number which must be displayed on the label, and can market the product.

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**ii** Some complementary medicines are made with relatively simple ingredients, such as acids, mineral salts, vitamins; whereas others are more complex, such as herbal materials and extracts.

**iii** Part 1 of Schedule 4 to the *Therapeutic Goods Regulations 1990*, provides that many listable goods may not have indications for the ‘treatment of a disease, condition, ailment or defect specified in Part 1 or 2 of Appendix 6 to the *Therapeutic Goods Advertising Code*’ (Advertising Code). Parts 1 and 2 of Appendix 6 to the Advertising Code outline a range of diseases, conditions, ailments and defects for which advertising representations are prohibited or restricted.
Following listing, the product may be subject to a TGA compliance review. The Act allows for cancellation of a product from the ARTG if the goods are ineligible for listing and/or a sponsor’s certification is incorrect.\textsuperscript{16}

\textbf{9.2.1.5 Presentation}

Complementary medicines must be presented for supply, including labelling and packaging, and in any advertising or information material, in accordance with section 3(1) of the Act. Presentation must comply with specific documents relating to medicine labelling requirements, including the:

- Therapeutic Goods Order No. 69 – General requirements for labels for medicines;
- Therapeutic Goods Advertising Code;
- Therapeutic Goods Regulations;
- Required Advisory Statements for Medicine Labels (RASML);
- \textit{Poisons Standards}; and
- TGA approved terminology for medicines.

The words that can/cannot be used, font sizes, standard warnings and required information are prescribed in detail in these documents. Medicine labels for listed medicines are not evaluated by the TGA before listing, but may be reviewed as part of compliance reviews. Medicine labels for registered medicines are evaluated by the TGA before market authorisation.\textsuperscript{17}

\textbf{9.2.2 Post-market requirements}

As with registered medicines, listed medicines are subject to post-market monitoring by the TGA. They may also be subject to a number of conditions which are imposed at the time the medicinal product is listed in the ARTG.

\textbf{9.2.2.1 Compliance with conditions of listing}

Medicinal products listed in the ARTG are required to meet a number of additional conditions of listing which are notified in writing to the sponsor of the listed product by the TGA. These include requirements that the sponsor:

- keep records relating to the listed medicine as necessary to facilitate the recall of any batch and to identify the manufacturer(s) of each batch;
- keep relevant GMP agreements in circumstances where any step in the manufacture of the product in Australia is sub-contracted to a third party who is not the sponsor;
• retain records of the distribution of the listed medicine for five years and provide the TGA with the records upon request;

• does not, by any means, advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the ARTG;

• notify the TGA about any reports of serious adverse reactions or similar experiences associated with the medicinal product as soon as practicable and retain records of such reports for at least 18 months from the day they are notified to the TGA;

• notify the TGA immediately where the listed product is distributed overseas as well as in Australia and it is subject to a product recall or any other regulatory action which has, or may have, relevance to the quality, safety or efficacy of the product in Australia;

• not supply the listed medicinal product after the expiry date of the goods; and

• only use specified colouring agents where the product is for ingestion and will be supplied in Australia.18

In addition to these general conditions, the TGA may impose conditions on a medicinal product relating to its specific ingredients.

9.2.2.2 Post-market monitoring

A multipronged, risk-based approach19 to the post-market monitoring of therapeutic products is undertaken by the TGA. It is intended to balance assurances for consumers and health professionals about the continuing quality, safety and efficacy of products included in the ARTG, ensuring access for consumers to medicines and minimising regulatory imposts on industry.

Post-market regulatory activity can be undertaken for ingredients, medicines and families of medicines. It draws on a combination of pharmacovigilance, adverse event and complaints reporting, and inspections of manufacturers which feed into risk-based sampling of medicines in the market place for testing.

9.2.2.3 Compliance reviews

Since medicines can be listed in the ARTG based on a self-declaration by the sponsor that they meet regulatory requirements, these products are subject to desk-based reviews, based on a proportion of newly listed medicines, to check their compliance early in the product lifecycle. These are either randomly selected by computer, based on a

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mathematical model; or are targeted for review based on outcomes of the random reviews, pharmacovigilance, adverse event reporting, complaints, and the compliance history of the sponsor.

In conducting a compliance review, the TGA may examine a range of information to assess the product’s compliance with legislative requirements. This may include product labels; product specifications; manufacturing formulae; the results of batch analyses; raw material specifications and certificates of analysis; the evidence held by the sponsor to support the indications and claims made in respect of the product; and websites to ascertain whether advertising for the product complies with the Therapeutic Goods Advertising Code.

Where the TGA review identifies that a product is non-compliant with legislative requirements, it can take a number of regulatory actions, including cancelling the product from the ARTG. If a medicine is cancelled from the ARTG, public advice of the cancellation is posted on the TGA website, and the product cannot be legally imported, exported, manufactured or supplied for use in Australia.

9.2.2.4 Advertising and promotion

The regulatory framework for medicines imposes restrictions on the advertising and promotion of therapeutic goods, including listed medicines. Issues in respect of advertising are discussed in Chapter Ten – Regulatory framework for the advertising of therapeutic products.

9.2.3 International regulatory frameworks

By their very nature, complementary medicines can encompass a wide range of products, with varying degrees and sources of evidence on their efficacy, and a history of use related to cultural and traditional values as well as on the basis of consumer health preferences. Whereas the regulation of registered medicines is well aligned globally, the international regulatory approaches to complementary medicinal products are often linked to national cultural and political values, and hence there is a high degree of variation in approaches.

Across these approaches, no one jurisdiction replicates the Australian regulatory approach of the NRA evaluating ingredients, and enabling self-evaluation of products. Nor is there consistency in the way jurisdictions categorise complementary medicinal products, the evidence paradigms, or require demonstration of good manufacturing practice. This divergence in regulatory approaches, particularly in relation to the sub-category of dietary supplements, makes direct comparisons on the time it takes to get a product to market and the associated regulatory burden difficult.

Regulation in the European Union (EU) allows multiple pathways to market for complementary medicines. The European Medicines Agency (EMA) regulates herbal medicinal products, but does not regulate vitamins and minerals (they are regulated as food
supplements). For low-risk, simplified registrations, products must only contain active ingredients from a list of permitted ingredients with conditions on their use. Where the sponsor of the herbal medicine draws on the phrase ‘well established use’ to support a marketing approval, indication claims can be made that are supported by that evidence. However for simplified registrations on the basis of ‘traditional use’, there are restrictions to permitted indications. Safety must be evidenced by a bibliographic review, and quality must be evidenced by compliance with medicinal GMP. Higher risk products achieve market approval through a full application and evaluation of scientific safety, quality and efficacy data (for the specified indications), and not on the basis of traditional use evidence. Monographs are established for both traditional use and well-established use products to enable simplified registration or bibliographic reviews.

In comparison, in Canada, complementary medicines are regulated as ‘natural health products’ by the Natural and Non-prescription Health Products Directorate (NNHPD), a division of Health Canada. Products include vitamin and mineral supplements, herbal preparations, traditional and homeopathic medicines, probiotics and enzymes. The regulations stipulate the substances that can be used, and market approval for the product is obtained by applying for a product license. The required evidence depends on whether the product makes a ‘modern health claim’ or ‘traditional medicine claim’, the risk profile of the product (in terms of the ingredient’s intrinsic properties, the product claims and health impact from the product not working as expected), and whether it complies with recognised monographs. Product quality must also be demonstrated by compliance with medicinal GMP standards. Products are classified into Class I, Class II or Class III, depending on the nature of the product and their efficacy evidence. Timeframes for evaluation of the product are related to its class, and range from two weeks to 30 calendar days, or within a 210 day period. The NNHPD also produces monographs to facilitate and simplify industry product license applications.

Internationally, the regulation of complementary medicines continues to evolve. Whether they are regulated as foods, supplements, traditional and herbal medicines or natural health products, there is a greater emphasis on the demonstration of evidence to support health claims, aligned with the general aims of improving the evidence base for the sector.

9.3 Assessment of current regulatory framework

In the regulation of complementary medicines, there is a natural tension between the desire to deregulate the industry, and the regulatory requirements necessary to meet the expectation of the Australian community that complementary medicines on the Australian market should be safe, of good quality, effective and widely available.

Scientific and history of established use information available in the public domain.
9.3.1 Views expressed by stakeholders

In submissions to the Review, some stakeholders raised concerns that there is a consumer perception that complementary medicines listed in the ARTG had been evaluated for efficacy by the TGA. However, as previously discussed (Section 9.2.1.4 refers), low-risk listed medicines obtain market approval without any pre-market assessment of the product by the TGA.

While most stakeholders agreed that the regulatory framework was appropriate to low-risk products, a number of views were expressed in regard to the following issues.

- The lack of regulatory capacity to refuse to list a product in the ARTG.
- The pharmaceutical grade GMP requirements are not commensurate with risk.
- The lack of availability of a modified market approval pathway for higher order therapeutic claims.
- The lack of transparency of the evidence requirements for efficacy claims. A significant proportion of consumers are not aware that the evidence base to support the efficacy claims of complementary medicines is not as comprehensive as for registered medicines, and unlike registered medicines there is no independent pre-market assessment of the evidence for listed medicines.
- The balance between pre-market and post-market regulation.
- Linkages between the complementary medicines regulatory framework and the advertising regulatory framework.
- The transparency of the regulatory process, timeframes for evaluation of new ingredients and the finalisation of compositional guidelines.
- Complexity for notifications of variations. Variations result in new AUST L/AUST R numbers, with associated costs, which are a barrier to innovation.
- The threshold for therapeutic goods for some complementary medicines.
- The lack of incentives for innovation.

The Panel notes that the TGA is currently undertaking a programme of reform for the complementary medicines framework arising from the 2011 Australian National Audit Office (ANAO) report and the TGA Reforms: A blueprint for TGA’s future (the Blueprint), which are relevant to some of the issues identified. The areas being addressed by the TGA reform work include updating guidance documents on the evidence required to support indications for listed medicines; collaborative work by the TGA and stakeholders to identify a catalogue of permitted indications from which sponsors of listed medicines can exclusively draw; and a new TGA-Industry Working Group on GMP (TIWGG), which is currently considering the automatic adoption and interpretation of the PIC/S GMP guidelines to Australian specific
conditions. As the TGA reform activity is running in parallel to this Review, the shape of the reform agenda may not have been known by all stakeholders who made submissions to the Review. It is noted that the outcomes of this work may address some of the concerns stakeholders raised with the Panel.

Notwithstanding, the Panel notes that while the regulatory framework for complementary medicines is largely sound and there is reform work under way, the framework could be improved in a number of areas. These issues are discussed below and can be broadly categorised as follows.

1. A need for the capacity to refuse listing before release to market, in addition to post-market delisting.
2. The pre-market assessment of new ingredients and of new complementary medicinal products (both listed and registered).
3. The ability to have appropriate therapeutic claims to be assessed by the NRA with consequent ability to make these claims to the public.
4. Enhanced transparency of the evidence held for therapeutic claims.
5. Enhanced transparency of processes and timeframes associated with listing.
8. Incentives for innovation.

9.3.2 The regulatory framework for complementary medicines

The continuing growth in the complementary medicines industry and uptake by consumers highlight the need to retain the regulatory framework to ensure that public health and safety is protected (Section 8.6 refers). Whilst listed products are considered to be ‘low risk’, they are not ‘no risk’, and some of the approved ingredients they contain can still pose serious health risks including toxicity and drug interactions.

While submissions from across all stakeholder groups expressed concerns with various aspects of the current regulatory framework (Section 9.3.1 refers), most reflected widespread support to retain the regulation of complementary medicines within the therapeutic goods framework, and that products that seek to make a therapeutic claim should be regulated as therapeutic goods.
The Panel supports the continuance of complementary medicines being regulated within the therapeutic goods legislative framework.

**Recommendation Thirty Three**

The Panel recommends that listed medicinal products, including complementary medicinal products, and the ingredients for use in such products, continue to be regulated within the therapeutic goods framework.

### 9.3.3 Capacity to refuse to list a therapeutic product

While marketing approval of listed products, based on sponsor self-certification rather than the independent assessment of a product’s safety, quality and efficacy, is commensurate with their low risk in the majority of cases, there is potential for market access to some products carrying indications which may conflict with current national public health priorities, such as anti-smoking or immunisation initiatives.

Under the Act, the Secretary (or delegate) must list the product in the ARTG, on certification by the sponsor that all legislative requirements have been met. There is no legislative basis on which the TGA can refuse to list the product. In the first report, the Panel recommended that it is an important public health safeguard to have the NRA retain sovereign responsibility for making decisions about Australian market access.

The Panel is of the view that it is appropriate for the NRA to retain the capacity to remove a listed product from the ARTG, as well as being given the capacity to refuse to list a product in the ARTG, where it has the potential to undermine public health efforts. The NRA will need to develop clear and transparent criteria that would enable it to make such a determination, and to provide this information in guidance materials.

**Recommendation Thirty Four**

The Panel recommends that the redrafted *Therapeutic Goods Act 1989* is amended to provide the NRA with the capacity to refuse to list in the ARTG complementary medicinal products and other listed medicinal products that have the potential to undermine Australia’s public health efforts.

### 9.4. Ingredients for listed complementary medicines

Market approval of listed products is established on a risk-based approach appropriate to low-risk products, comprised solely of approved ingredients and manufacture under GMP. In this context, maintaining an adequate level of regulatory control and protection for Australian consumers relies on the pre-market evaluation of the safety and quality of the ingredients, and post-market monitoring and compliance activities.
There are approximately 10 new ingredients approved for use in listed medicines each year compared to between 1,500 and 2,000 new complementary medicinal products listed annually in the ARTG. The requirement for a pre-market evaluation of new products would represent a far greater regulatory burden to industry than the current pre-market approval of new ingredients.

The Panel notes that there would be little value in a pre-market evaluation of the efficacy at the ingredient level as that can alter when combined with other ingredients in a product. As such, efficacy evaluation is best undertaken at the product level.

### 9.4.1 Evidence requirements for new ingredients

The Panel is of the view that safety and quality of new ingredients should be evaluated by the NRA. However, as new ingredients are not the same as new chemical entities, the rigour of evidence requirements do not need to be the same as for registered medicines. The current range of evidence that is accepted is limited and should be expanded. Other forms of evidence that may be acceptable include internationally recognised papers and articles about ingredients, and recognised monographs, for example, those developed by Health Canada for ‘natural health products’. Some internationally recognised traditional medicine pharmacopoeia may also be appropriate, noting that those based on a tradition of use do not always include a sufficient demonstration of safety, and additional information may be required of the sponsor.

The NRA should work with stakeholders to develop criteria to identify appropriate evidence sources, which may change over time. Any criteria developed should take into account whether there is sufficient demonstration of safety and quality, and include consideration of evidence.

#### 9.4.1.1 Good Manufacturing Practice

The Panel determined that it is appropriate to maintain quality controls for active ingredients for use in listed medicinal products, through compliance with PIC/S GMP standards. Whilst these standards were developed in the context of registered pharmaceutical medicines and their active ingredients, the principles are appropriate to the quality assurance of approved ingredients and listed complementary medicinal products. Automatic adoption of PIC/S GMP standards and revisions provides the complementary medicines sector with more clarity on GMP requirements, and promotes GMP consistency across the Australian sector. In revising the Act and subordinate legislation (Recommendation Twenty Eight), the Australian Government may wish to consider making provision within the Act for the automatic adoption of PIC/S GMP standards and revisions.

The Panel is supportive of the work agenda of the TIWGG and the appropriate application of PIC/S GMP to the sector, which reflects the risk profile of low-risk active ingredients. This includes using a risk rating algorithm to quantify the most relevant risks for the
manufacturer, and a stratified approach to managing compliance and inspection regimes (including reinspection intervals), instead of a ‘one size fits all’ approach. The Panel considers that the NRA should agree a mechanism to ensure that these modifications continue to apply to revised PIC/S GMP standards, except in circumstances where this has the potential to undermine product quality or safety.

The Panel also notes that TiWGG will enable real time consultation with industry on proposed PIC/S revisions, and the development of clear, concise and consolidated guidance for sponsors and manufacturers on PIC/S GMP, in parallel with the revision process. The guidance should be easily accessed and understood by a range of audiences, including small to medium sized enterprises.

**Recommendation Thirty Five**

The Panel recommends that the NRA continues to evaluate ingredients for use in listed medicinal products, and requires listed medicinal products to only include ingredients that have been approved for use in listed products. In undertaking an evaluation of ingredients, the NRA should continue to give consideration to:

A. the safety of the proposed ingredient, taking into account factors such as: proposed dosage; route of administration; frequency and duration of administration; and possible drug interactions;

B. working with stakeholders to identify a broader range of appropriate sources of evidence for the quality of new ingredients, which may change over time; and

C. the quality of the proposed ingredients, including proposed methodology for ensuring product purity, consistency, stability and other aspects of the PIC/S GMP.

**9.4.1.2 Adoption of overseas approvals**

Some industry stakeholders consider that, despite different international regulatory approaches, utilising overseas approvals would reduce the duplication of regulatory effort involved with assembling the necessary safety and quality data for new ingredient applications.

The Panel considers that to be consistent with the approach recommended for registered medicines, in addition to a sponsor seeking a de novo evaluation of a new ingredient data package, the sponsor should be able to utilise a report from a comparable overseas NRA. In doing so, the sponsor would submit an un-redacted evaluation report from a comparable overseas NRA with a copy of the data package provided to that NRA. The sponsor would also need to submit data to address any Australian specific requirements. The NRA’s evaluation should be restricted to the extent required to demonstrate that the approval is for the identical form, dose and route of administration of the ingredient being applied for, and the
Australian specific data. Any time savings will be dependent on the extent of that additional evaluation.

To implement this approach, the international regulatory differences must be taken into account to develop a set of transparent criteria to identify a comparable overseas NRA or assessment, for the purpose of ingredient (and product) assessments. The same broad principles described at Recommendation Five should apply where they are appropriate to the low-risk profile of listed medicines.

With the international trend towards greater regulation of traditional medicines, and the development of more expansive evidence bases, there may be greater regulatory harmonisation in the future. This may help identify comparable overseas regulators.

**Recommendation Thirty Six**

The Panel recommends that a sponsor seeking to have a new ingredient assessed by the NRA for use in listed medicinal products, including complementary medicinal products, is able to either:

A. submit data relating to the safety and quality of the proposed ingredient for use in listed medicinal products for de novo assessment by the NRA; or

B. submit an un-redacted evaluation report from a comparable overseas NRA, along with a copy of the dossier submitted to that NRA and data supporting specific Australian requirements, such as labelling, to the Australian NRA for assessment (refer to Recommendation Five). The Australian NRA to make a recommendation regarding use of the ingredient in listed medicinal products once it has considered the data within the Australian context.

**Catalogue of approved ingredients**

The TGA publication, *Substances that may be used in Listed medicines in Australia*, is a 305 page document that includes the active, excipient and component ingredients that may be used in listed medicines. The document alphabetically lists all approved ingredients and their restrictions. Whilst it states that it may be updated from time to time, the Panel noted that this last occurred in December 2007.

For a sponsor to determine which products are approved and their conditions of use, if they are not included in this publication, they would need to know to check and cross reference several sources containing information on conditions of use and other relevant issues. For small to medium sized enterprises, this is particularly onerous and confusing, with potential for a sponsor to miss a notification that an ingredient is approved. The Panel is of the view that information related to approved ingredients should be consolidated into a ‘one stop shop’, easy to locate catalogue for sponsors and other interested parties to access. It should be available online, maintained in real time, and cover the active and excipient ingredients.
and all conditions and restrictions for use. The TGA is currently developing such a catalogue, and the Panel strongly supports its implementation as a priority.

**Recommendation Thirty Seven**

The Panel recommends that the NRA develop and maintain, in real time, a catalogue of approved ingredients for use in listed medicinal products that is readily accessible to sponsors and the general public.

### 9.5 Market approval of complementary medicinal products

Listed complementary medicinal products are solely composed of approved ingredients and may only carry low level indications for therapeutic use that are limited to self-limiting, non-serious conditions. While those requirements underpin their low-risk status, they are not without risk, and the current regulatory framework applies a risk-based approach to their market approval. As such, sponsors can list a product on the basis of a self-declaration that all legislative requirements are met, and that the indications are supported by evidence.

#### 9.5.1 Permitted Indications for listed medicines

Stakeholders generally support the implementation of a Permitted Indications list from which sponsors can solely draw to describe the low level indications permissible for listed medicines. They recognise the need to overcome the potential for use of misleading claims which the current free text option in the ELF allows, and which may be promulgated in product promotions.

Sponsors must hold evidence for indications entered into the ARTG, but a report of outcomes for compliance monitoring by the TGA in the 2014 calendar year showed one in five products selected for a compliance review failed to comply with the evidence requirements for indications. The Panel is aware that the TGA has previously consulted with stakeholders through formal consultations and TGA/industry working groups to develop a list of Permitted Indications. The comprehensive list was drawn from existing indications coded in the ELF, industry input through consultation, and from indications used in monographs in the EU, Canada and Japan. Given the expanded indications to select from, it was planned that implementing the Permitted Indications will include removing the free text field, subject to the outcomes of this Review.

Some stakeholders believe the list of Permitted Indications is not comprehensive enough. Some industry stakeholders also expressed concerns that the list would limit sponsors in the

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vi Through the TGA Permitted (coded) indications for listed medicines Consultation Paper in 2013; the Office of Complementary Medicines Industry Consultation Group; the Informal Working Group on Complementary Medicines; and the TGA Complementary medicines reforms: Standard/coded indications project - pre consultation phase in 2012.
market differentiation of their products, and impact on the ‘fast to market’ approach in cases where a sponsor wishes to use an indication that is not in the list. This issue can be addressed by requiring legislative changes to add new indications at regular timeframes.

Other stakeholders have suggested that non-compliance may be through a lack of understanding of the regulatory framework and could be addressed through better industry education and guidance, and that wilful misuse should be managed through strengthened compliance and enforcement actions.

Stakeholders who support the Permitted Indications consider that unsubstantiated claims for product indications are damaging to the reputation of the sector as a whole, including those sponsors that comply with the rules.

The Panel is of the view that all listed complementary medicines that are not subject to pre-market efficacy review by the NRA should be limited in the indications that they may make. The Panel considers that the use of Permitted Indications and the removal of free text fields will prevent sponsors from inadvertent non-compliance. Additionally, these requirements are consistent with international regulatory approaches, such as the permitted indications allowed for traditional herbal medicines in the United Kingdom (UK).

The Panel also recognises there are additional benefits associated with using Permitted Indications. They are sufficiently flexible to enable sponsors to have market differentiation through the use of qualifying terms to identify the context of the therapeutic use, and enable the use of ‘scientific’ or ‘traditional’ indications, depending on the evidence used to support the therapeutic use.

The Panel recommends implementation of the Permitted Indications project with an appropriate transition period for all products to move to the new system.

**Recommendation Thirty Eight**

The Panel recommends that the NRA establishes the list of Permitted Indications, from which sponsors must exclusively draw, for listed medicinal products in the ARTG.

### 9.5.2 Stakeholder views on including complementary medicines in the ARTG

Most stakeholders have indicated that the level of TGA pre-market assessment for listed products is appropriate, as long as post-market compliance monitoring and enforcement is strengthened. Some have commented, however, that an independent pre-market verification by the regulator of the safety, quality and efficacy of complementary medicines is needed to adequately protect consumers.

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[vii] Scientific indications rely on evidence from systematic reviews, reports of clinical studies, peer-reviewed published review articles, and pharmacopoeias and monographs. Traditional indications are those that rely on evidence based on long term use for at least three generations; observation; and refinement of dosage and formulations through experience – TGA Evidence Guidelines 2014.
Other stakeholders have proposed that an additional market entry pathway be introduced for complementary medicines for which sponsors wish to claim higher level indications than permitted for listed medicines, but which are not at the same level of risk as registered complementary medicines. They contend that the safety and quality of listed medicines with higher level indications is assured as they would be comprised solely of ingredients approved for listed medicines, and be produced under GMP. As such, they would not need the rigorous pre-market assessment applied to registered complementary medicines, and a less onerous and costly process for sponsors would create more opportunities for innovation and increased export sales.

Some industry stakeholders also expressed the view that pharmaceutical grade GMP requirements for listed products are not commensurate with the level of risk. They assert it is either not required as the ingredients comprising the product were manufactured under GMP, or that an intermediary level of GMP between pharmaceutical level GMP and food standards GMP should be developed for complementary products.

Most stakeholders, however, supported the current PIC/S GMP standards for any products claiming to have therapeutic effects, on the same basis as outlined in Section 9.2.2.2, with some qualifications. They put forward that the processes for product stability, validations, and release for supply are the areas in which PIC/S GMP can be more efficiently adapted for controls on products manufactured in the Australian context, through the TIWGG.

### 9.5.3 Options for including complementary medicines in the ARTG

The Panel considers that there should be three options for sponsors to have complementary medicines included in the ARTG.

The first option, for listed medicines with lower level indications, is largely similar to the current requirements for listing. The only difference is that sponsors must exclusively draw on permitted indications (Recommendation Thirty Eight refers). The Panel considers that with this addition, the suite of pre-market controls on complementary medicines with low level indications would provide adequate protection for consumers on the safety, quality and efficacy of products available on the market, and that the added regulatory burden of an independent pre-market assessment is not warranted.

A second option for listing in the ARTG should be established for sponsors to list products for which they hold evidence to support indications that exceed the permitted indications, and where they meet all the requirement of listed medicines. For example, a sponsor may wish to claim that a listed product ‘lowers cholesterol’, which is at a higher level than to claim the product ‘may assist in the maintenance of cholesterol within the normal range in healthy individuals’. Currently, to make higher level claims a sponsor needs to meet the substantial evidence requirements and costs to register the product.
The Panel considers that there are a number of benefits to establishing a process and incentives for the development of complementary medicines with proven efficacy for higher level indications. Firstly, consumers would have access to a wider range of evidence-based remedies to self-manage their health, with potential improvements to broader public health outcomes. Secondly, the expansion of the evidence base for listed complementary medicines provides greater transparency to health professionals and consumers about evidentiary bases for claims, which improves confidence in the sector. Finally, sponsors would have a solid regulatory underpinning and a market advantage in promoting these innovative products.

The Panel recommends that the current suite of requirements for registered medicines are also retained as Option Three for sponsors that seek approval for higher risk complementary medicines with associated higher level claims.

9.5.3.1 A hierarchy of evidence commensurate with the indications claimed

The Panel considers that whilst Option One and Option Three are broadly consistent with the current processes, the implementation of the three options will introduce a hierarchy of evidence as the basis for a graded response to the risk profile of complementary medicines and the associated indication claims that can be made. For Option One, there will be a low level of evidence; for Option Two, an intermediate level of evidence; and for Option Three, a higher level of evidence.

For Option One, a self-regulatory approach will enable a sponsor to self-declare they meet all the legislative requirements for a listed product, including using only permitted indications, and holding evidence to support the efficacy of the product for those indications. Neither the application nor efficacy evidence is assessed by the NRA.

For Option Two, the point of difference will be that indications can exceed the permitted indications on the basis of a pre-market evaluation of the evidence of efficacy. The Panel is of the view that any product carrying indications that exceed the permitted indications for therapeutic use, requires an independent pre-market evaluation of the supporting evidence. The level of rigour in evaluating products submitted for listing in the ARTG under Option Two will need to be established, and the criteria for the appropriate evidence should be determined by the NRA in consultation with stakeholders.

For Option Three, the submission of a complete evidence package, consistent with requirements for registered products, would be evaluated by the NRA.

For products listed under Option One or the proposed Option Two, the approved product would still gain an AUST L number, denoting the lower level of risk and regulatory evaluation, compared to the AUST R number on registered products.
Recommendation Thirty Nine

The Panel recommends that there be three options by which sponsors may seek entry into the ARTG of complementary medicinal products and other listed medicinal products for supply in Australia.

Option One
Listing in the ARTG following self-declaration by the sponsor of the safety and quality of the product in circumstances where:

A. the product contains only ingredients that have been previously approved by the NRA for inclusion in listed medicinal products; and
B. the ingredients, including proposed dosage where applicable, route of administration, and duration of use where applicable, comply with listing notices or similar documents issued or endorsed by the NRA; and
C. the ingredients comply with any compositional guidelines or other compendial standards issued, adopted or approved by the NRA; and
D. the product is manufactured in accordance with PIC/S GMP; and
E. the sponsor only seeks to make claims regarding the indications for use of the product selected from the list of Permitted Indications (Recommendation Thirty Eight refers); and
F. the sponsor holds evidence to support these indications, consistent with requirements outlined in the evidence guidelines issued by the NRA from time to time.

Option Two
Listing in the ARTG following a self-assessment of the safety and quality of the product, and following assessment of the efficacy of the product by the NRA, in circumstances where:

A. the product contains only ingredients that have been previously approved by the NRA for inclusion in listed medicinal products; and
B. the ingredients, including proposed dosage where applicable, route of administration, and duration of use where applicable, are compliant with listing notices or similar documents issued or endorsed by the NRA; and
C. the ingredients comply with any compositional guidelines or other compendial standards issued, adopted or approved by the NRA; and
D. the product is manufactured in accordance with PIC/S GMP; and
E. the sponsor seeks to make health claims that fall outside the list of Permitted Indications but which are still appropriate for listed medicinal products; and
F. the sponsor can provide evidence acceptable to the NRA to support the safety and efficacy of the product for the proposed indication(s), commensurate with risk. This may include the submission of an un-redacted evaluation report(s) from a comparable overseas regulator.

Option Three
Registration of a complementary medicinal product in the ARTG following an assessment by the NRA of the product for safety, quality and efficacy in accordance with existing requirements for registration of complementary medicines (Recommendation Forty refers).
9.5.3.2 Good Manufacturing Practice for products

The Panel notes that the safety of a medicinal product relates not only to the intrinsic safety of its component ingredients but also the product manufacturing process. Safe ingredients can be contaminated by the unintended inclusion of other substances due to poor manufacturing quality assurance processes.

The Panel concluded that the current PIC/S GMP requirements for listed and registered complementary medicines ensure the consistent, high quality standard of therapeutic products manufactured under GMP license and inspection mechanisms, and ongoing GMP compliance. It also results in a positive reputation for the regulator, Australian manufactured products, and trade advantages for sponsors and the Australian economy. As such, the Panel agrees that the NRA should retain PIC/S GMP for all complementary medicinal products included in the ARTG, and that any local adaptions of PIC/S standards should continue to be managed by the appropriate NRA/stakeholder forum such as the current TIWGG.

9.5.3.3 Comparable overseas regulators’ approvals

The Panel considers that to be consistent with the regulatory frameworks for medicines and medical devices, sponsors of complementary medicines should have the capacity to utilise product assessments from comparable overseas regulators, in addition to submitting an application for a de novo assessment by the NRA. This would normally apply to Option Two and Option Three.

Recommendation Four of this Review made provision for the NRA in making regulatory decisions about medicines, to utilise information from the un-redacted assessment reports of comparable overseas regulators as long as certain principles are fulfilled. Those principles, set out in Recommendations Five, Six and Seven in regard to identifying comparable regulators and utilising elements of their reports, will also apply to the assessment of complementary medicines.
Recommendation Forty

The Panel recommends that where a sponsor seeks to include a complementary medicinal product in the ARTG that the sponsor is able to do so utilising registration Pathways One or Two, namely:

<table>
<thead>
<tr>
<th>Pathway One</th>
<th>Submission of a complete dossier for de novo assessment. This assessment may be undertaken in full by the Australian NRA or via a work-sharing arrangement between the Australian NRA and a comparable overseas NRA.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathway Two</td>
<td>Submission of an un-redacted evaluation report from a comparable overseas NRA, along with a copy of the dossier submitted to the comparable overseas NRA and Australian specific data similar to that provided by sponsors in Module 1 of the Common Technical Document, for assessment by the Australian NRA. The Australian NRA to make a recommendation regarding registration of the complementary medicinal product once it has considered the data within the Australian context.</td>
</tr>
</tbody>
</table>

9.6 Improving processes and timeframes

Stakeholder submissions and consultations raised concerns regarding the lack of transparency of processes and legislative timeframes for the assessment of a new ingredient for listed complementary medicinal products; finalisation of compositional guidelines; and the assessment of registered complementary medicines.

9.6.1 Timeframes for assessing new ingredients

Stakeholders commented that the lack of predictable timeframes for assessment of new ingredients represented a barrier to bringing innovative products to market. Specifically, stakeholders argued that the lack of timeframes meant that it was difficult for sponsors to plan for the rollout of a new listed product containing the new ingredient. Additionally, stakeholders also expressed concern over the lack of transparency of the process and status of new ingredient applications. Advice provided by the TGA indicates that the delays in the approval of new complementary medicinal ingredients are largely due to the quality of submissions received, particularly in relation to the type and format of data provided. Given that the application fees are related to the number of pages in the data submission (Section 9.2.1.1 refers), there is a financial disincentive to the sponsor providing a detailed submission at the start of the application.

The Panel agrees that legislated timeframes will give a greater degree of predictability for sponsors, and would be consistent with the operation of other parts of the therapeutic goods framework. In determining the appropriate timeframes, the NRA, in consultation with stakeholders, should give consideration to:
the NRA developing clear and consolidated guidance on data requirements for applications and the evaluation criteria and process;

- introducing a requirement for the submission of data in a standardised format consistent with the internationally recognised CTD;

- pre-submission meetings; and

- revision of the application fee structure so that it is no longer based on a per-page basis.

Stakeholders also commented on the time required for a sponsor to develop and assemble the required data package. The Panel is of the view that by allowing a broader range of acceptable evidence and introducing a fee structure that is not dependent on the volume of submissions, the quality of applications and hence the assessment times will improve. Utilising comparable overseas assessments may also reduce this timeframe (Section 9.4.1.2 refers).

The timeframe for NRA decision-making should be reflective of the low-risk nature of the proposed new ingredient and the level of evidence required for assessment of a new ingredient for safety and quality. Given the evidence requirements for a new ingredient are lower than for a new chemical entity for a registered medicine, the timeframes for evaluation should be considerably shorter than the 255 working days that are applicable to registered medicines. The Panel considers that the timeframes for assessment of the different classes (Class I, II or III) of natural health products in Canada (Section 9.2.3 refers) would be an example of appropriate timeframes that are commensurate with the risk profiles.

9.6.2 Timeframes for finalisation of Compositional Guidelines

Compositional Guidelines (Section 9.2.1.1 refers) are used for an approved active or excipient ingredient where there is no default standard recognised in the Act. They are designed to assist sponsors in understanding the nature of the ingredient, whether their material conforms to the requirements for that ingredient, and in minimising the risks associated with that ingredient by complying with the parameters of that guideline.

Stakeholders have commented on the process and timeframes for completing the sponsor created Compositional Guidelines. The current consultation process adds lengthy delays to their finalisation. This is particularly problematic where the Compositional Guideline is for a new complementary medicine ingredient, as any delay in finalisation adds to uncertainty about use of the new ingredient, potentially delaying market access for sponsors who wish to conform to the guideline.
The Panel is of the view that the consultation period for Compositional Guidelines should be removed and that they should be finalised within a defined period (for example, within three months).

9.6.3 Timeframes for assessing new complementary medicinal products

Stakeholders also raised the fact that there is no prescribed timeframe for assessing a newly registered complementary medicine. While registered prescription and over-the-counter (OTC) medicines have prescribed timeframes (255 working days for a full evaluation), these timeframes do not apply to registered complementary medicines. While there is no prescribed statutory timeframe for evaluation, stakeholders argued that an evaluation can take one to two years to complete.\(^{33}\) The TGA indicates that that ‘the complexity of the substance, the adequacy and the quality of the data submitted in the application will all influence the length of time required for evaluation.’\(^{34}\)

The Panel understands that the TGA is having discussions with the complementary medicines industry in relation to how evaluations of registered products are conducted and the extent to which safety and quality data needs to be re-evaluated; for example, in cases where ingredient safety and quality have already been evaluated, but an evaluation could be limited to examining safety in the context of the specific route of administration. While the Panel notes these issues, for the reasons outlined above, the development of prescribed timeframes would significantly enhance predictability for industry. Such timeframes will also be required for consideration of listed products using Option Two.

As such, the Panel considers that the NRA should develop, in consultation with stakeholders, agreed approaches to improving the quality of submissions and agreed timeframes for assessments of complementary medicines under both Option Two and Option Three. This consultation should involve:

- the NRA developing clear and consolidated guidance on data requirements for applications and the evaluation criteria and process;
- consideration of the format for submission of applications for new Option Two, including enhancements to the ELF modules for the submission of an appropriate data package to support claims that are not included in the Permitted Indications;
- introducing a requirement for the submission of data for registered complementary medicines under Option Three in a standardised format consistent with the internationally recognised CTD; and
- encouraging greater informal engagement between the NRA and sponsor, including through pre-submission meetings and non-binding meetings.

\(^{33}\) Australian Regulatory Guidelines on Complementary Medicines
The timeframes should also reflect that the time for evaluation of data will be significantly less under Option Two than for Option Three. The Panel considered that the timeframes for assessment of the different classes of natural health products in Canada (Section 9.4.2 refers) may be an example of appropriate timeframes that are commensurate with the risk profiles.

In the Panel’s view, a lack of clear, concise and consolidated guidance is also contributing to unpredictable and elongated timeframes. Good guidance materials are extremely important because the complementary medicines framework is complex, and much of the industry in Australia is comprised of small to medium sized enterprises that do not have internal regulatory affairs capacity. Despite the availability of sponsor and TGA pre-submission meetings and a large volume of guidance material, it can be difficult to locate all relevant information and navigate the application process. The Panel is of the view that the NRA should continue to engage with stakeholders, including through industry education and pre-submission meeting opportunities, and develop improved guidance materials to enable timelier processing of high quality applications.

**Recommendation Forty One**

The Panel recommends that the NRA develops, in consultation with industry, legislative timeframes for the:

A. assessment of new ingredients for use in listed medicinal products;
B. publication of finalised compositional guidelines for newly approved ingredients for use in listed medicinal products, where appropriate;
C. assessment of medicinal products listed under Option Two; and
D. registration of medicinal products under Option Three.

### 9.7 Risk-based approach to managing variations

Some industry stakeholders commented that the process for making modifications or variations to listed and registered complementary medicines is not risk-based. They asserted the process was a disincentive to making variations to available products, and a barrier to Australian consumers’ access to products with potential to enable better health outcomes. Under the current regulatory framework, sponsors must notify the NRA of any changes or variations in respect of information about the medicine. For listed complementary medicines, the majority of changes are completed online via the ARTG or the ELF system. However, if a variation creates a separate and distinct good, the sponsor must complete a new listing. This applies in circumstances where a sponsor makes a change to the active ingredient; the quantity of an active ingredient; or the dose. Additionally, the Regulations define that changing characteristics such as the product name or indications are not considered variations under the current framework.

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ix This is defined in section 16 of the *Therapeutic Goods Act 1989* (Cth).
(among other things) will result in a new product. As stakeholders noted, this will result in a new AUST L number for the complementary medicine, and the sponsor must update the packaging and labelling of a product to reflect the new AUST L number.

For listed complementary medicines, some changes may be managed under the provisions of the Therapeutic Goods (Groups) Order No. 1 of 2001, where goods can be ‘grouped’ under an existing ARTG entry, and the existing AUST L number is maintained. Additionally, the current ELF system allows for some flexibility to record information that removes the need for the sponsor to notify the NRA of potential changes. An example is the capacity to nominate multiple GMP-compliant manufacturing sites at the time of listing, which enables the sponsor to use alternative manufacturers in accordance with business needs.

The Panel notes that for registered complementary medicines, variations are managed the same way as for prescription medicines.

The Panel recommends that the NRA should, in consultation with industry, implement a risk-based approach to variations of registered and listed complementary medicines. It should be consistent with the approach to variations for prescription and OTC medicines (Recommendation Thirteen refers). For listed products, implementation of this approach may include enhancements to the ELF, to manage variations that do not affect the safety and quality of the product. Any new approach should consider products approved to make higher level claims under the Panel’s proposed Option Two, including abridged assessments limited to only those aspects that establish the continued safety, quality and efficacy of the complementary medicine.

**Recommendation Forty Two**

The Panel recommends that, consistent with Recommendation Thirteen, the NRA adopt a risk-based approach to the management of variations to complementary medicines listed in the ARTG. This approach should provide for:

A. notification of variations to the NRA in circumstances where the variation does not impact the quality, safety or efficacy of the product; or

B. assessment of the variation by the NRA in circumstances where the variation has the potential to impact the safety, quality or efficacy of the medicine. This assessment to be abridged in scope, so that only those aspects that require evaluation in order to establish the continued safety, quality and efficacy of the complementary medicine following implementation of the proposed variation are examined (abridged assessment).
9.8 Demonstrated evidence of efficacy

9.8.1 Improved access to evidence of efficacy

Consumers reasonably expect that the medicines they consume are safe, high quality, and effective for the indications for which they make claims.

The efficacy of some complementary medicinal products is underpinned with scientific evidence. Others rely on evidence of traditional use. It can be difficult for consumers to discern the difference. There is also a common perception that products are natural and, therefore, safer than conventional medicines; and that their efficacy has been evaluated by the regulator. These beliefs contribute to a lack of consumer awareness of their potential risks.  

Consumers need to be able to make health and expenditure decisions that result in better health outcomes. Stakeholders commented that many consumers are confused by the volume of information available on complementary medicines, and where to look for substantiated information.

Some industry representatives also noted that efficacy data is published on their websites or in promotional materials to help inform consumers’ health care decisions. Others commented that publishing their efficacy data would provide their competitors with the advantage of being able to use that evidence, without undertaking their own research.

The Panel notes that, as a condition of listing, sponsors are required to hold the evidence to support product indications. This information should be published on the sponsor’s website in a format accessible to consumers or, if the sponsor does not have a website, on another site to be determined by the NRA.

The presentation of the information and the data to be disclosed will need to be determined by the NRA in consultation with stakeholders. Prescription medicines undergo a pre-market evaluation of the efficacy evidence. An Australian Public Assessment Report (AusPAR) is published to outline the evaluation and considerations that led to product approval. Given their low-risk profile, however, listed complementary medicines do not warrant public disclosure at that level of detail. At a minimum, the published information should include a summary of the evidence being used, including a bibliography of publicly available information, with citations of journal articles (noting the original articles may be subject to copyright) and links to published data where available. Additionally, the Panel considers that other materials, similar to Consumer Medicines Information (CMI) and Product Information (PI), may be appropriate to some complementary medicines, and the NRA should encourage industry to utilise these tools where they would be effective.

Industry considers that the primary issue affecting the sector is excessive regulatory burden and the Panel is aware that requiring the publication of efficacy evidence may be
perceived as an increase in that burden. However, the Panel is of the view that as the evidence is already held by sponsors, its publication will broaden the accessible evidence base of the sector.

This requirement will not be out of step with developing international requirements. For example, the *Natural Health and Supplementary Products* regulatory framework in New Zealand will also require the publication of a summary of evidence in relation to any health claims. This measure increases the incentive for industry to work with the NRA to develop efficacy monographs, similar to the approach of other countries such as the EU and Canada. Sponsors will be able to refer to the monographs as their efficacy evidence, and the increased effort required to publish evidence data held by sponsors should be offset by the benefits and reduced regulation associated with using the monographs (Recommendation Forty Six refers).

**Recommendation Forty Three**

The Panel recommends that where a medicinal product is listed in the ARTG, the sponsor be required to publish on the sponsor’s website or, if the sponsor does not have a website, on another website nominated by the NRA, the evidence that it holds to support all indications included in the ARTG entry.

### 9.8.2 Improved transparency about the type of evidence supporting product efficacy

The type of evidence used to support a listing depends on the nature of the indication, including whether the evidence is based on scientific or traditional use paradigms (defined at Section 9.5.1), and the specificity of the indication. Traditional medicines are influenced by cultural values and belief systems, and for many traditional medicines, there is often little established scientific data that can be used to support the traditional indications.

There was a divergence of views among stakeholders regarding the use of required statements to advise consumers on the evidence and evaluation status of a product. Stakeholders were split between those who supported and opposed either positive statements or disclaimers on labels and promotional materials. Those in support asserted such information would inform health care decisions and spending, and improve health outcomes. Those who opposed stated that overseas experience showed low level consumer recognition of label disclaimers, and cited the business costs associated with country-specific labelling changes.

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\x In the context of replacing pharmaceutical marketing restrictions with label disclaimers, the disclaimers were not considered an adequate way of informing patients about the efficacy and safety of drugs.
Internationally, regulators have acknowledged consumers’ right to be informed about the evidence for the efficacy of a product. In the EU, sponsors of traditional herbal medicines are required to include a specific set of words on product labels where the indications are based exclusively on evidence of long standing use as a traditional remedy. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) also requires this statement to be in promotional and advertising material. Similarly, in the United States (US), the Food and Drug Administration (FDA) requires that some dietary supplements include a label disclaimer that the claim ‘has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease’, because only an evaluated drug can make that claim.

In Australia, the National Medicines Policy states that, to achieve optimum use of medicines, ‘consumers and health practitioners should have timely access to accurate information and education about medicines and their use’. For complementary medicines, the label and promotional materials are the primary source of information for consumers at the time of purchase on when and how to use them.

The Panel agrees that transparency about efficacy claims empowers consumers in making health care decisions, and is paramount. There should also be regulatory incentives for the sector to build a quantifiable scientific evidence base for complementary medicines.

Accordingly, the Panel considers that for complementary medicines listed in the ARTG under Option One, there should be a prominent disclaimer on the sponsor’s website and promotional materials which reflects, in plain language, that the efficacy of the product has not been independently assessed. For products that are listed on the basis of traditional evidence, the disclaimer should also clearly state that the efficacy claims are based on traditional use.

**Recommendation Forty Four**

The Panel recommends that where a medicinal product is listed in the ARTG under Option One (self-assessment), the sponsor is required to include a prominent disclaimer on all promotional materials relating to the product, including product information on websites, to the effect that the efficacy claims for the product have not been independently assessed and/or are based on traditional use.

9.8.3 Incentives to improve the evidence base

As discussed at Section 9.5.3.1, the Panel is of the view that introducing an evidence hierarchy to the complementary medicines framework will create an opportunity for sponsors to lift the standards of evidence and extend the evidence base for the sector.

Sponsors’ efforts in this regard should be recognised and acknowledged by enabling them to state on promotional materials, including labels, that the NRA has evaluated the efficacy
claims. Doing so will improve transparency about the status of efficacy claims; bring the NRA actions into alignment with public expectations; and provide sponsors with a positive marketing advantage.

**Recommendation Forty Five**

The Panel recommends that where a medicinal product is listed in the ARTG following an assessment by the NRA of an application under Option Two, the sponsor is able to indicate on all promotional materials and on the product label, that the efficacy of the product has been independently assessed for the approved indication(s).

### 9.8.4 Established efficacy evidence – monographs

The consensus of industry stakeholders is that the current requirement for each sponsor to hold evidence for each complementary medicine is overly burdensome; particularly where the product contains well-known active ingredients that have a history of effective use. Effectively, multiple sponsors conduct systematic reviews and literature searches of the same evidence, creating unnecessary regulatory burden. To address this duplication of effort, stakeholders called for the NRA to allow for internationally recognised monographs to be relied upon as evidence for specific (non-general) indications. In particular, stakeholders argued that single ingredient monographs and product monographs produced by Health Canada could be used as efficacy evidence.

Additionally, some stakeholders suggested that the NRA could, in consultation with industry, develop evidence monographs for indications for common ingredients (at various dosages). This would eliminate the requirement for sponsors to conduct systematic evidence reviews each time they wished to market a product containing such an ingredient.

The Panel agrees with stakeholders that the regulatory burden could be lowered through developing a set of nationally recognised monographs. As such, the Panel is of the view that the NRA, in consultation with industry, should determine a work programme for developing evidence monographs for complementary medicine ingredients that are in most demand, and where the efficacy evidence of a particular ingredient for an indication is well established. Additionally, the Panel recommends that the NRA recognise or adopt evidence monographs developed by comparable regulators on a case-by-case basis.

These monographs should contain a summary of the traditional and/or scientific evidence of efficacy, along with other relevant information such as the dosage range and duration of use. Sponsors would still be required to hold additional information to demonstrate that the complementary medicines product was of sufficient quality. As discussed above, such monographs could be adopted from those developed by overseas regulators, or they could be based on existing sources such as Cochrane Reviews.
Recommendation Forty Six

The Panel recommends that the NRA develops or adopts from comparable overseas regulators, efficacy monographs for commonly used active ingredients that have been approved for use in listed medicinal products. Such monographs would document the evidence supporting the efficacy of the ingredients for specific indications and other relevant information.

9.9 Review and appeal rights

A further issue raised by stakeholders is the absence of a formal review and appeal right in relation to applications for assessments of new complementary medicines ingredients. Under section 60 of the Act, any person who is affected by an ‘initial decision’ of a delegate may request a review of that decision by the Minister (or delegate), with further appeal rights to the Administrative Appeals Tribunal available if required. This process applies to any decision relating to listing, registration, variation or cancellation of a therapeutic good (amongst other decisions), including complementary medicinal products. However, this process does not apply to the assessment of new ingredients.

The Panel considers that review and appeal rights should also be available in relation to the proposed power for the NRA to refuse to list a product based on public health policy (Section 9.3.3 and Recommendation Thirty Four refer). These review rights should be consistent with the existing review rights for products under section 60 of the Act.

The Panel recommends that review and appeal rights be made available in relation to applications for assessment of new ingredients approved for use in listed complementary medicines, and they should be consistent with the same review and appeal rights for registered medicines. However the existing section 60 appeal mechanism would not be appropriate for new ingredients, as the range of ‘interested parties’ could potentially extend to a large number of people, and create significant uncertainty in the predictability of the application progress. This could be overcome if the review and appeal rights are restricted to the person who made the application only. This approach would allow for appropriate review of such decisions whilst ensuring that the NRA was not exposed to review requests from a potentially large class of people, tying up NRA resources in responding to appeals. This could be implemented in conjunction with the Panel’s proposed review of the Act and subordinate legislation (Recommendation Twenty Eight refers).

xi New complementary substances are evaluated under section 16GA of the Therapeutic Goods Regulations, and thus do not fall within the definition of an ‘initial decision’ as set out in section 60(1) of the Therapeutic Goods Act 1989 (Cth).
Recommendation Forty Seven

The Panel recommends that, in revising the *Therapeutic Goods Act 1989* and subordinate legislation (Recommendation Twenty Eight refers), the Australian Government provides review and appeal rights for the sponsor who has lodged an application for a new ingredient (to be approved for a listed medicine) to seek a review of an NRA decision regarding that application.

9.10 Appropriate regulatory framework for very low-risk therapeutic products

Given the low-risk profile of complementary medicinal products, stakeholders have suggested some products are better suited to regulation under either general consumer law or as a food. It was also noted that products regulated under consumer law or food regulation were not subject to medicinal manufacturing standards, significantly decreasing costs for industry. Furthermore, stakeholders also raised the fact that since the introduction of *Standard 1.2.7 – Nutrition, Health and Related Claims* in 2013, which allows for both general health claims for food goods and high level claims that refer to osteoporosis and neural tube defects, it could be argued that food goods are able to make higher level health claims than similar low-risk complementary medicines.

Most stakeholders were not in favour of a blanket policy of moving low-risk complementary medicines products to either the regulatory framework for food products (if applicable) or to general consumer goods regulation. In particular, stakeholders argued that while some complementary medicines may be low risk, because they are marketed as medicines and make health claims, it is important that they be regulated under the therapeutic goods framework.

The Panel considered evidence that for some sub-categories of low-risk complementary medicinal products, there can be stratification of risk within that sub-category, based on the ingredient dosage, or its interactions with other substances. For example, at a certain dosage, some substances are classified as a Schedule 4 substance under the *Poisons Standard*. As such, the product specific risks (for products containing such substances) would not be easily addressed under general consumer law.

Consistent with the recommendations made in relation to low-risk (non-complementary) medicines (Recommendation Fourteen refers), the Panel proposes that the Australian Government reviews the parameters for low-risk listed complementary medicines, with a view to ensuring that products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act.

Such a review would need to consider the risk profile of individual products, and assess whether particular risks could be appropriately managed under alternative regulatory
frameworks on a case-by-case basis. It would also need to consider whether the advertising controls in the therapeutic goods regulatory framework would be required to manage that risk. The review would have the benefits of clarifying the regulatory approach for individual products for consumers, industry and health professionals, and minimise inconsistencies across regulatory frameworks.

**Recommendation Forty Eight**

The Panel recommends that the Australian Government undertakes a review of the range of complementary medicinal products, currently listed in the ARTG and subject to regulation under the medicines framework, with a view to ensuring that products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act.

### 9.11 Post-market monitoring

#### 9.11.1 Stakeholder views

Submissions to the Review reflected the widespread support of consumers, health professionals and many industry stakeholders for the design of the TGA’s post-market monitoring strategy. Most stakeholders indicated, however, that post-market monitoring is currently under resourced and would be more effective if elements of the strategy were strengthened. Given that there is no independent pre-market evaluation of listed complementary medicines, post-market monitoring is a key control on the ongoing safety and quality of a product.

Post-market monitoring activities relate to pharmacovigilance, and to compliance investigation and enforcement. Pharmacovigilance is a critical component of the regulator’s post-market activities, capturing data of real world use to inform future use of a product to ensure adequate consumer protections.

Stakeholder views linked the high level of non-compliance with regulatory requirements, with the small chance of being reviewed and insufficient penalties for non-compliance. The level of compliance monitoring is relatively low, and is further impaired by sponsors being able to withdraw a product from the ARTG once notified of the review. Once a product is withdrawn, the compliance review is terminated, and the level of product compliance while it was on the market is not assessed.

#### 9.11.2 Reforms to address high levels of non-compliance

The Panel notes that compliance reviews over the past decade have shown that non-compliance with legislative requirements continues to be high.\(^{xii}\) Most recently in 2015,

\(^{xii}\) ANAO 2011 Audit noted that in 2006 and 2009 post-marketing monitoring by the TGA identified 75 per cent and 90 per cent of non-compliance respectively.
the Department of Health reported that, between January and December 2014, 61 per cent of products that were subjected to a targeted review were found in breach of regulatory requirements, as were 27 per cent of products selected randomly for review.\textsuperscript{48} It is unsurprising that the targeted reviews yielded higher non-compliance rates.

For the 121 products found to be non-compliant, 189 breaches occurred. Of this, 44 per cent were breaches about labelling and advertising requirements; 21 per cent on the evidence requirements for the indications claimed; 7 per cent on the product formulation, manufacturing or quality requirements; 4 per cent on incorrect information included in the ARTG entry; and 24 per cent on other breaches including safety requirements such as the sponsor failing to comply with a condition that the medicine is subject to, or an additional condition of listing.\textsuperscript{49}

The Panel considers that given the nature of the breaches, non-compliance would be mitigated to some extent by the implementation of earlier recommendations of this Review. Recommendation Thirty Eight requires sponsors to draw from a set list of Permitted Indications for products with low level claims. Recommendation Thirty Nine requires listed products with higher level claims to undergo pre-market testing for safety, quality and efficacy. Recommendations Forty Three and Forty Four provide for promulgation of information on whether the efficacy of the product has been independently assessed. Issues related to labelling and advertising were also of concern, and are discussed in Chapter Ten.

The Panel recommends that random and targeted reviews continue to be identified on a risk-benefit basis and that the proportion of random and targeted reviews is increased. Further, if there is an improvement in compliance as a result of the implementation of the recommendations above, it is anticipated it will have the flow-on effect of releasing regulatory resources from compliance action.

The Panel also notes the widespread support across all stakeholder cohorts for curtailing the ability of sponsors to withdraw products from the ARTG once the intention to undertake a compliance review is notified or under way. The Panel recommends that amendments should be made to the regulatory framework to enable the NRA to complete the post-market monitoring of a product withdrawn from the ARTG after the sponsor is notified of an impending review. This measure will remove the incentive to withdraw and re-list a product to avoid a compliance review.

\textbf{9.11.3 Communicating compliance outcomes to stakeholders}

To be effective in ensuring consumer safety, the outcomes of post-market compliance reviews and of complaints resolution outcomes must be promptly communicated to consumers, health professionals and sponsors. Currently the TGA reports on its website the cancellation of listed or registered products from the ARTG (as an outcome of compliance activity), and determinations of the Complaints Resolution Panel. The Review Panel notes that the TGA is considering how broader information on the outcomes of post-market
compliance review can be made publicly available, and the Panel considers that the NRA should continue to progress this work.

9.11.4 Targeting compliance monitoring activities to risks

Another source of efficiencies in utilising regulatory resources to establish these changes is the better alignment of regulatory resources to managing the level of risk. For example, the lifecycle of a listed product can be short and seasonal and, for products using newly approved ingredients, some risks may only become apparent in real world use while the product is on the market. The Panel recommends that the risk algorithm for post-market monitoring should prioritise compliance reviews early in the market life of these products.

The issues raised in Recommendation Twenty Seven on the features of a comprehensive and efficient post-market monitoring system are also relevant to post-market monitoring of complementary medicines. These features include the timely analysis of data from existing datasets, such as de-identified data from the Pharmaceutical Benefits Scheme; Medical Benefits Scheme; eHealth and hospital records; complaints management processes; and the communication of risks and electronic transmission of adverse events reports. The Panel notes that the TGA currently works with overseas regulators to target emerging compliance problems. The Panel recommends that the NRA continues to work towards greater cooperation with overseas regulators in this regard, as the international harmonisation agenda continues to be progressed.

Recommendation Forty Nine

The Panel recommends that the NRA develops a more comprehensive post-market monitoring scheme for listed medicinal products, including complementary medicinal products. Such a scheme should include:

A. an increase in the number of products subject to random/targeted post-market review;
B. provisions to allow the NRA to complete a post-market review in the event that the sponsor withdraws the product from the ARTG during the course of the review;
C. timely availability of information for consumers for each listed product in relation to whether the product has been subject to post-market review, and the timing and outcome of any review;
D. integration and timely analysis of any available datasets, including eHealth and hospital records, to provide a more streamlined and cost-effective approach to post-market monitoring (Recommendation Twenty Seven refers), particularly of products including newly approved ingredients;
E. provision for electronic reporting of adverse events; and
F. enhanced collaboration with overseas NRAs to share information relating to safety or efficacy of comparable products.
9.12 Incentives for innovation

A consistent theme emerging from a number of stakeholder submissions was that the current regulatory framework for complementary medicines does not provide sufficient incentives for companies to invest in research and development. Stakeholders argued that this was particularly the case in relation to registered complementary medicines, which unlike new chemical entities generally do not meet the conditions for patent protection and, as such, it was particularly difficult to recoup the significant costs of developing a data package for regulatory approval.

Additionally, stakeholders pointed out that the data protection period available for certain registered medicines under section 25A of the Act is not available for listed complementary medicines and generally also not available for the smaller number of registered complementary medicines. If the data protection period applies to a medicine containing an active ingredient, then the TGA is not permitted to rely on any data submitted in order to approve a different product for a period of five years. As such, the five-year data protection period available in the Act aims to prevent ‘free-riding’ by sponsors of generic medicines by preventing a company from submitting an application to market a medicine with the same active ingredient without independently providing safety and efficacy data to the NRA.xiii

However, data protection is only available for active ingredients included in registered medicines that have never been in the ARTG. As many registered complementary medicines do not contain entirely new active ingredients,xiv they are also usually not covered by the data protection period available under section 25A of the Act.xv Stakeholders argued that the absence of a data protection period (or alternatively, some form of market exclusivity period) means that there is insufficient incentive to register complementary medicines with documented health claims, as there is no mechanism to prevent ‘free-riding’ by subsequent sponsors.

Similarly, stakeholders argued that the current system does not provide protection against ‘free-riding’ for sponsors that expend significant time and money in getting a new complementary medicine ingredient approved, as once a compositional guideline is published, another company can simply match the specification in the guideline without having to invest in generating the underlying evidence. As such, stakeholders argued that the current regulatory framework does not provide sufficient incentive for sponsors to

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xiii If the data protection period is not applicable and there is no patent covering the active ingredient, a sponsor of a generic medicine can rely on the safety and efficacy data already provided to the TGA in support of an application for marketing approval, provided that they demonstrate bioequivalence to the original medicine.
xiv For example, a registered complementary medicine may contain the same active ingredient(s) as a similar listed complementary medicine, but be registered because the sponsor has submitted a data package to justify making higher level claims in relation to the medicine.
xv Per section 25A(2) of the Therapeutic Goods Act data protection is only available for information relating to an active ingredient that has never previously been included in a product in the ARTG.
generate the evidence required to receive higher regulatory approval (e.g. approval of a new complementary medicines ingredient and/or registration of a product in the ARTG).

The Panel notes that the current regulatory framework does not restrict the complementary medicines industry from developing greater evidence in order to meet the standards for registration. However, the Panel recognises the concerns of stakeholders that the current system does not encourage industry investment in generating greater evidence in relation to complementary medicines ingredients and products. The Panel agrees with the view of stakeholders that encouraging greater development of evidence relating to complementary medicines would have the benefits of greater consumer confidence in the efficacy of complementary medicines, and the improved reputation and competitiveness of the sector domestically and internationally. It is possible that the Panel’s recommended new Option Two approval process (Recommendation Thirty Nine refers), and its recommendations relating to improving guidance and implementing prescribed approval timeframes (Recommendation Forty One refers), as well as enabling sponsors to promulgate higher level claims for efficacy (Recommendation Forty Five refers), may assist in increasing incentives for companies to bring forward applications.

While the Panel notes the view of a number of stakeholders that the Australian Government should consider implementing measures to encourage innovation (such as data protection or market exclusivity), the Panel’s terms of reference do not permit it to make specific recommendations relating to such issues.

Furthermore, proper examination of such proposals involves considering a wider set of issues than could be considered in the timeframe for this Review. These include the cross-portfolio policy responsibility for such issues (i.e. between the Department of Industry and the Department of Health), the complexities involved in the interaction of the patent system and data protection provisions, and the role of multilateral and bilateral trade agreements in governing Australia’s intellectual property framework.

As such, the Panel does not make a specific recommendation in favour of any particular mechanism to encourage innovation. Instead, the Panel recommends that the Australian Government gives consideration to providing incentives for innovation as part of the Industry, Innovation and Competitiveness Agenda. This issue could be examined by an expert working group, or by existing forums.

**Recommendation Fifty**

The Panel recommends that the Australian Government gives consideration to improving the competitiveness of the Australian complementary medicines industry by providing incentives for innovation.
9.13 Increased transparency of decision making

The Minister may seek the advice on any matter relevant to complementary medicines from a range of stakeholders through the Advisory Committee on Complementary Medicines (ACCM). The ACCM is established under the Regulations, and comprises up to 12 members each with expertise in at least one of the fields of complementary medicine practice; the manufacture of medicines; consumer issues; general medical practice; herbal medicine; naturopathy; nutrition and nutritional medicine; pharmacology; pharmacognosy; toxicology; and epidemiology.

The functions of the committee are, at the request of the Minister or Secretary, to provide advice about the approval of new ingredients, and the inclusion, variation, continued retention or removal of a complementary medicine from the ARTG. The committee may also be required by the Minister or Secretary to give advice to other parties.

Few stakeholders commented directly on the advisory committee arrangements but were generally supportive of the ACCM having a membership of experts drawn from a wide range of relevant fields. Some noted that the ACCM has not met for over a year and does not currently have members drawn from all required disciplines. Some stakeholders advocated for separate expert committees for specific disciplines.

In considering the views on the role, functions and membership of the ACCM, the Panel recommends that this committee should be retained in its current form as a statutory committee with advisory functions. Additionally, the Panel noted that the Regulations already provide for an appropriate range of experts to participate as members of the committee. Participation in regular meetings of the ACCM by the full range of experts prescribed in the Regulations would be in line with the objectives of the Transparency Review to ‘raise stakeholder involvement in the TGA’ (page 4), and the Blueprint reforms to ‘deliver transparent stakeholder engagement in regulatory policy making on emerging issues’ (page 4).

The advantages of a cross-discipline committee include achieving a whole-of-sector view and consistency in the application of regulatory principles. With the emergence of a number of traditional medicine disciplines in Australia (for example, Ayurveda and Unani medicine), the composition of the ACCM should be regularly reviewed to ensure it retains the appropriate range of skills to provide advice on both long standing and emerging areas of complementary health practice in Australia. Ensuring stakeholder participation in advice on regulatory policy development will underpin public confidence in the NRA’s decisions.
Recommendation Fifty One

The Panel recommends that the statutory Advisory Committee on Complementary Medicines is retained, and that the committee:

A. is composed of a range of experts across relevant fields and consumer representation, as required over time;
B. at the request of the NRA, provides advice regarding the inclusion, variation, removal of complementary medicinal products from the ARTG and any other matters relating to complementary medicines; and
C. takes into account any other information that the committee considers is material to its deliberations.

5 Therapeutic Goods Administration (2015, May), op. cit., p. 56.
8 Therapeutic Goods Administration (2015, May), op. cit., p. 56.
9 Ibid., pp. 58-59.
10 Ibid., pp. 50-51.
15 Ibid., pp. 27-31.
16 Therapeutic Goods Administration (2015, May), op. cit., pp. 53-54.
17 Ibid., pp. 28-30.
18 Ibid., pp. 49-50.
Chapter Nine: Regulatory Framework for Complementary Medicines

19 Ibid., 39-40.
23 Ibid.
27 World Health Organization (2013), op. cit.
32 Ibid.
34 Therapeutic Goods Administration (2015, May), op. cit., p. 56.
36 Ibid.
41 Ibid., pp. 11-16.


Ibid.


*Therapeutic Goods Regulations 1990*, Part 6, Division 1E, section 39A(2).
CHAPTER TEN: REGULATORY FRAMEWORK FOR THE ADVERTISING OF THERAPEUTIC PRODUCTS

10.1 The current regulatory framework for advertising therapeutic products

The advertising of therapeutic products to the public is regulated under the Therapeutic Goods Act 1989 (the Act), the associated Therapeutic Goods Regulations 1990 (the Regulations), the Therapeutic Goods Advertising Code 2007 (the Code); the Poisons Standard; and the Competition and Consumer Act 2010 and other relevant laws. Therapeutic products include medicines and medical devices.

Given the limits on the pre-market assessment of products listed in the Australian Register of Therapeutic Goods (ARTG), controls on advertising claims for the use, efficacy and benefits of products are an important part of protecting the public’s health and financial wellbeing. The regulatory framework provides for advertising controls, supported by post-market monitoring (Section 9.11 refers) complaints management through a Complaints Resolution Panel (CRP) and industry associations (Section 10.4.3 refers), and sanctions and penalties administered by the Therapeutic Goods Administration (TGA) for breaches of regulatory requirements (Section 10.4.4 refers).

The Code defines an advertisement as ‘any statement, pictorial representation or design, however made, that is intended, directly or indirectly, to promote the use or supply of the goods’.¹ This includes advertisements in magazines, newspapers, television, radio, the internet, posters, billboards or journals.

The advertising framework is designed to establish a balance between providing access for consumers to information that supports their health care decisions, and a safety net to ensure that therapeutic products are used safely, with guidance from health care practitioners where appropriate.

Consistent with the risk-based approach to the regulation of therapeutic products, the regulatory controls on advertising increase in line with the potential risks to health of using a product. While advertising to consumers is permitted for medicines available for sale over-the-counter (OTC), it is prohibited for prescription medicines and certain pharmacist only medicines.

The current controls on advertising are exercised under a three-tiered system in which the TGA has overall responsibility for maintaining and administering the Act, Regulations and Code; co-regulation of some aspects of advertising is undertaken by government in partnership with key stakeholders; and self-regulation occurs under industry associations’ codes of practice.
The co-regulation system is representative of all key stakeholder groups: namely consumers, health professionals, industry sectors, media, advertisers and government. These groups have different responsibilities under the Act, the Regulations and the Code. The system of co-regulation involves:

- the Therapeutic Goods Advertising Code Council (TGACC) overseeing the Advertising Code, and providing advice on policy and procedural matters to government on advertising;
- industry associations assessing certain advertising for ‘pre-approval’ and managing complaints about ‘below the line’ advertising (such as leaflets, catalogues, point of sale materials etc.);
- the TGA and the CRP investigating complaints about alleged breaches of the Regulations for mainstream advertising (such as print and broadcast media); and
- the TGA undertaking monitoring and compliance activities, including enforcement.

The TGACC is a high level partnership group with membership that comprises the manufacturing and supplier sectors, the advertising industry, consumers, health care professionals and government. It is responsible for advising government on a range of policy and procedural matters including:

- maintaining the currency and relevance of the Code;
- setting uniform standards in approval processes and advertising;
- responses to submissions from sponsors wishing to have their products carry health claims in respect of serious illnesses; and
- appeals on approval decisions.2

While the promotion of products to health professionals is outside the parameters of the regulatory framework, all advertising of therapeutic products directed to consumers must comply with the Code. The Code establishes a number of objectives: advertising is to be conducted in a way that promotes the quality use of therapeutic goods; is socially responsible; and does not mislead or deceive consumers.3 The Code also sets out a number of principles about what advertisements must do (including only making claims that the sponsor has verified) and must not do (including among other things arousing unrealistic expectations about product effectiveness, encouraging self-diagnoses, and implying the product cannot cause harm or side-effects).4 This is in line with similar objectives and principles set out in advertising regulations in other comparable countries including the United States (US), the United Kingdom (UK) and Canada.

The Code also indicates that advertising which makes claims of efficacy for a product in respect of a small number of serious illnesses (such as HIV AIDS) is prohibited. Claims in respect of a larger number of other serious illnesses (such as cardiovascular disease) are
restricted, in that they must not be made unless prior formal approval of the regulator is obtained.\textsuperscript{5}

The pre-approval of advertising for OTC medicines, including complementary medicines, is undertaken through a co-regulatory mechanism. This involves delegates of the Secretary of the Department of Health (the Secretary), located in industry associations,\textsuperscript{1} approving some advertising material prior to promulgation. Although advertising of all therapeutic products to consumers is covered by the Code, pre-approval is not required for the advertising of medical devices, or for any therapeutic product on the internet, subscription television or in below-the-line materials such as leaflets, flyers, catalogues, brochures, shelf talkers, letter box drop or at point of sale.

Some aspects of the advertising controls are self-regulatory. The complaints panels of industry associations manage complaints under voluntary codes of conduct about under-the-line advertisements (e.g. leaflets, point of sale etc.) placed by their members. Sponsors who are non-compliant with their compliance decisions may be referred to the TGA for compliance action. For sponsors who are not members of industry associations, and referred to the TGA for non-compliance, the TGA seeks resolution through administrative processes in the absence of regulatory controls.

The majority of complaints about advertisements directed to the public, however, are received, considered and determined by the CRP, which is established under the Regulations and comprises representatives from industry, consumers, health care professionals and government. It is chaired by a nominee of the TGACC, and its secretariat is provided by the Australian Self Medication Industry (ASMI) but funded by the TGA.

Under the Regulations, where the CRP upholds a complaint, it may request the withdrawal or retraction of the material, and the promulgation of a correction. If this request is not complied with within 14 days, the matter may be referred to the Secretary for compliance action.

10.1.1 International regulation of therapeutic goods advertising

While there is some divergence in approach, most international jurisdictions regulate therapeutic goods advertising to protect the public from harm, for example by maintaining restrictions against advertisements that are misleading and deceptive. The approach to regulating advertising varies between self-regulatory and co-regulatory approaches. The regulatory mechanisms include pre-vetting advertisements prior to publication, processes for managing complaints, and enforcement in respect of specific product categories (for example a herb or a vitamin) and methods of promulgation (through radio, internet or print

\textsuperscript{1} Currently the industry associations are the Australian Self Medication Industry (ASMI) and Complementary Healthcare Council of Australia (CHC).
International jurisdictions vary as to which products and methods of promulgation (e.g., internet, print, television, etc.) are covered by the NRA’s advertising regulatory framework. In some jurisdictions, all therapeutic goods that are advertised to consumers in any format are regulated by the NRA. For example, in New Zealand medicines, medical devices and related products that are advertised are regulated by Medsafe, with pre-approval under the Therapeutic Advertising Pre-vetting Service (TAPS) for advertisements published in mainstream media. Similarly in Canada, medicines, natural health products and medical devices advertisements are covered by Health Canada’s regulatory framework.

By contrast, in the UK while the advertising of medicines is specifically regulated by the Medicines and Healthcare products Regulatory Agency (MHRA), medical devices advertising is regulated in part under general consumer law and in part by codes of broadcast and non-broadcast advertising.

In the US, while the Food and Drug Administration (FDA) is responsible for prescription medicines advertising, regulation of OTC medicines advertising and dietary supplements advertising is the responsibility of the Federal Trade Commission (FTC).

10.2 Assessment of the current regulatory framework for advertising therapeutic goods

The Panel is of the view that, given the limits on pre-market assessment for low-risk products, controls on advertising under the legislative framework for therapeutic products provide an important assurance that consumers have access to accurate information in making health care choices.

Although stakeholders have expressed a range of views in submissions to the Review about the features, processes and administration of the advertising framework for therapeutic products, embedding controls on advertising, complaints management and compliance in legislation is widely supported. The establishment of a regulatory underpinning for advertising controls, although administered in a variety of ways, is also consistent with the approach taken in other comparable countries such as the UK, Canada and the US.

Recommendation Fifty Two

The Panel recommends that advertising of therapeutic products to the public continues to be regulated by the NRA under a legislative framework which includes an advertising code.

While medical device advertisements are not covered by Canada’s pre-vetting system, they are subject to the advertising regulations in the Canadian Food and Drugs Act.
10.3 Prescription and pharmacist only medicines

Current advertising controls increase as the risks to health increase through use of a therapeutic product. In Chapter Four, the Panel considered the regulatory framework for prescription medicines (under Schedule 4 or 8 of the Poisons Standard) and pharmacist only medicines (under Schedule 3 of the Poisons Standard) including in relation to advertising.

In Section 4.3.6, the Panel recommends that the Australian Government retain the current ban on direct-to-consumer advertising of prescription medicines. The Panel accepts the view widely expressed by consumers, health professionals and industry, that allowing direct-to-consumer advertising of prescription medicines is not in the public interest.

Currently direct-to-consumer advertising is also prohibited for pharmacist only medicines, except in respect of a very small number for which the active ingredients/substances are listed in Appendix H of the Poisons Standard. The Panel noted that there was no clear consensus among stakeholders as to whether or not the current general restriction on direct-to-consumer advertising of Schedule 3 medicines should remain. Nor did the evidence available to the Panel conclusively demonstrate the potential for either widespread harm or benefit from relaxing the restriction.

The Panel concluded that for the present time the restriction on the advertising of most pharmacist only medicines should be retained while a review of the Schedule 3 Advertising Guidelines is undertaken, in consultation with states and territory governments, and in concert with a review of the Scheduling Policy Framework. The aim of the recommended review is to provide for the development and adoption of a formal risk-benefit methodology for the assessment of Schedule 3 substances including consideration of the inclusion in Appendix H of the Poisons Standard, and to streamline the processes for re-scheduling.

Recommendation Fifty Three
The Panel recommends that advertising to the public continues to be prohibited for Schedule 4 and 8 prescription medicines, and the advertising of medicines in Schedule 3 of the Poisons Standard continues to be prohibited except those products containing ingredients set out in Appendix H (Recommendation Twelve refers).

10.4 Enhancements to the design and features of the advertising framework

While the legislative basis for the regulation of advertising is supported, the features and administration of the current framework have been subject to sustained criticism by consumers, health professionals and industry, documented in a series of reviews undertaken over the past decade, and reiterated by submissions to this Review.
10.4.1 Inconsistencies in the application of the advertising regulatory framework

An issue raised by many stakeholders is the complexity of the advertising regulatory framework. For example, the agency to which a sponsor must apply for a pre-approval of an advertisement is dependent on the advertising media chosen (radio advertisements for complementary medicines are pre-approved by ASMI, while print media advertisements are pre-approved by the Complementary Healthcare Council of Australia (CHC)) or the product type (print media advertisements for OTCs are approved by ASMI).

In the case of a multimedia campaign for the same medicinal product, a sponsor needs to seek pre-approval from more than one body. Complaints may also be managed by multiple bodies. This may result in inconsistent decisions and time and cost delays for the sponsor in having the campaign approved.

Figure 16 provides an overview of the complexities of the pre-approval and complaints management processes under the current advertising framework.

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iii While the Complementary Healthcare Council of Australia (CHC) is now known as Complementary Medicines Australia, the CHC has delegated authority under the Regulations for advertising.
Figure 16: Current Australian advertising and complaints flow chart

Advertising Pre-Approval

Non-prescription Medicines

Direct-to-consumer

OTC & complementary medicine advertisements on radio and free TV

OTC medicines advertisements outdoors, print media, cinema and other public displays

Complementary medicines advertisements outdoors, print media, cinema and other public displays

ASMI*  
ASMI*  
CHC*

*Assessed against the Regulations and Advertising Code

Current complaints pathway

Promotion exclusively to health care professionals

Direct-to-consumer advertisements

Mainstream print, internet, email, SMS, radio, TV including pay TV, cinema, billboard, posters

Below-the-line i.e. letterbox, leaflet, flyers, point of sale, in-store displays etc.

Relevant industry Code of Conduct

CRP against TG legislation including Advertising Code

ASMI (OTC & CMs), CHC (CMs) or MTAA (medical devices) industry Codes of Conduct

Still non-compliant

TGA can consider any form of advertisement including for illegal products, irrespective of whether it is directed to consumers or health professionals. This includes complaints about non-industry association members’ advertising.

Recommendation to Secretary

TGA can consider any form of advertisement including for illegal products, irrespective of whether it is directed to consumers or health professionals. This includes complaints about non-industry association members’ advertising.
A further complexity is the inconsistency between the advertising requirements for medical devices and medicinal products. While medical device advertisements must comply with relevant parts of the Act, Regulations and Code, they are not subject to a pre-vetting process prior to publication. Instead, sponsors of medical devices are responsible for ensuring that advertisements are consistent with the intended purpose for the device which the sponsor certified when the device was included in the ARTG. Sponsors of medicinal products, however, are required to submit their advertisements to an Advertising Services Manager in ASMI or the CHC to seek pre-approval that the depiction of the product is consistent with the indications which the sponsor certified when listing the product in the ARTG.

The Panel notes the impact of the different pathways for handling approvals and complaints, and recommends that future requirements for advertising therapeutic products to consumers are made consistent for all forms of advertising for both medicines and medical devices.

**Recommendation Fifty Four**

The Panel recommends that the future requirements for advertising therapeutic products to the public are made consistent for all medicines and medical devices.

### 10.4.2 Pre-approval process

The complexities noted in Section 10.4.1 about the pre-approval arrangements increase the burden associated with complying with regulatory requirements.

While some industry stakeholders support the pre-approvals process as a safety net against inadvertent non-compliance with the Code, they concede that this process needs modification. They suggest that a single body be established for all pre-approvals. Such a body would preferably have expertise and networks in advertising, and staff with the requisite skills for assessing whether an advertising claim aligns with the product’s approved indications. It would manage pre-approvals regardless of the form of the advertisement or type of media in which it was placed. This proposal would be similar to the New Zealand TAPS arrangements.

Others consider that the pre-approval process is an unnecessary regulatory burden which should be abolished as it creates delays for the sponsor in promoting a product already on the market, and does not protect sponsors against being found non-compliant with the requirements of the Code.

These stakeholders have proposed arrangements similar to those in the US, whereby compliance with regulatory requirement for advertising is the responsibility of the sponsor, and non-compliance is identified during post-market monitoring or the complaints process.
10.4.2.1 International approaches to pre-vetting of advertisements direct-to-consumers

While pre-vetting of advertisements is not undertaken by some regulators such as the FDA or the FTC in the US, a number of other jurisdictions have forms of pre-vetting or pre-approval systems for the advertising of medicines direct-to-consumers.

In Canada, the pre-vetting of medicines advertisements is administered through an ‘independent, self-regulatory and voluntary system’. Advertisements are pre-vetted by accredited agencies that comply with Health Canada criteria, including having written policies and procedures and standards to ensure accurate assessment of advertising materials consistent with legislation, and an objective and timely complaints system, amongst other things.

In New Zealand, pre-vetting of advertisements is run by the Association of New Zealand Advertisers under the TAPS. A TAPS approval must be obtained from a TAPS adjudicator or a delegate internal to the sponsor’s company who has been authorised to provide approval prior to publication of the advertisement in mainstream media. Pre-vetting under the TAPS system does not, however, guarantee that a sponsor or publisher will be found compliant with the legislation and regulations at a compliance review.

In contrast, the advertising of medicines direct-to-consumers in the UK is managed under a co-regulatory model that provides for regulation by the MHRA and self-regulation through Codes of Practice administered by industry associations. Under this approach, the MHRA has statutory powers to require companies to submit advertising materials for pre-approval.

The Proprietary Association of Great Britain (PAGB) (the peak body representing manufacturers of branded OTC medicines and food supplements in the UK) administers a consumer advertising Code of Practice. It is a condition of membership that all OTC medicine advertising must comply with the code.

10.4.2.2 Pre-approval benchmarks

In Australia, the timeframes for advertising pre-approvals through ASMI or the CHC are often extended where a sponsor must seek pre-clearance for some advertisements or campaigns through more than one agency, including the TGA. The agencies endeavour to undertake an advertising pre-clearance within a standard legislated timeframe of between 10 to 60 working days. In practice, they strive to give first round feedback within five working days. For minor changes to existing approvals, the applications can be fast tracked.

In the UK, advertisers seek pre-clearance on a voluntary basis by their trade association of self-regulatory body, or through the MHRA. These agencies have a target timeframe of
within five working days. In 2014-15, the MHRA achieved the target for 99 per cent of items submitted.\textsuperscript{15}

Health Canada pre-clearance is done by accredited agencies that attest they meet specific criteria, including timely processing. Pre-clearance timeframes are regularly four days, or for a higher fee, can be done as a priority, within 24 hours or same day.\textsuperscript{16}

Table 9: Advertising pre-clearance comparison

<table>
<thead>
<tr>
<th>Country</th>
<th>Pre-clearance Agency</th>
<th>Target number of days</th>
<th>Performance against target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>ASMI</td>
<td>10 – 60 days, or in a day for priority applications</td>
<td>Not reported</td>
</tr>
<tr>
<td>Australia</td>
<td>CHC</td>
<td>10 – 60 days, or in a day for priority applications</td>
<td>Not reported</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>MHRA</td>
<td>5 working days</td>
<td>99% achieved</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>PAGB</td>
<td>1-5 working days</td>
<td>Not reported</td>
</tr>
<tr>
<td>Canada</td>
<td>accredited agencies, for example, Advertising Standards Canada</td>
<td>4 days or within 24 hours to 2 business days for priority applications</td>
<td>Not reported</td>
</tr>
</tbody>
</table>

\textit{10.4.2.3 Pre-approvals or self-regulation in Australia}

The Panel is of the view that the pre-approval mechanism should be abolished to ease regulatory imposts on sponsors, on the condition that other recommended protections for consumers are implemented.

These protections include advertising claims being consistent with the permitted or approved indications specified when a product is included in the ARTG (Recommendation Thirty Eight refers); strengthening of post-market monitoring (Recommendation Forty Nine refers); improving the complaints management process (Recommendation Fifty Six refers) and strengthening sanctions and penalties available to the NRA (Recommendation Fifty Seven refers).

Whether an advertisement conforms to the Code and the approved indications will be assessed in terms of the advertisement’s ‘probable impact upon the reasonable person to whom the advertisement is directed’.\textsuperscript{17}

**Recommendation Fifty Five**

The Panel recommends that the whole process of vetting and pre-approval of the advertising of therapeutic products to the public is stopped in favour of a more self-regulatory regime.
10.4.3 Complaints management

Health care providers and consumer advocates have raised a number of concerns about the complaints handling system: it lacks transparency about complaints outcomes; timeframes for complaint resolution are overly long; a number of bodies are involved, causing confusion about lodging a complaint; and the sanctions and penalties available to the regulator are ineffective.

Industry stakeholders also regard the process as complex, with long resolution timeframes, and lacking consistency in decision making.

Complaints about advertisements directed to the public on free to air television, radio, the internet, newspapers, magazines, displays (except inside individual shops) and cinematographic films are managed by the CRP. Complaints about advertisements directed to consumers in all other media (e.g. leaflets, brochures, catalogues, shelf talkers) are managed by industry complaints panels in each sector (Figure 16 refers).

Where the CRP finds a complaint justified it may request a withdrawal or retraction of the material, and the promulgation of a correction. It does not have the power to impose penalties. If the request is not complied with within 14 days, the CRP may make recommendations to the Secretary who may order withdrawal of the advertisement or the publication of a retraction or correction. The CRP may also recommend that the Secretary order an advertiser not to repeat misrepresentations. For continuing non-compliance, regulatory action to remove the product from the market may be necessary. When the decision-maker acts on a recommendation, the action can be challenged by seeking a ministerial review followed by an appeal to the Administrative Appeals Tribunal.18

10.4.3.1 International approaches to managing complaints

Some jurisdictions such as Canada have a self-regulatory approach to complaints management. Complaints are generally managed by accredited agencies. However, where health and safety risks are identified, the agencies are required to refer complaints to Health Canada.

Similarly, in New Zealand complaints may be made to the New Zealand Advertising Standards Authority.

By contrast, in the UK a co-regulatory approach is applied, in which complaints can be made to a range of self-regulatory bodies or the MHRA. Bodies that may hear complaints include industry associations, the MHRA, and the UK Advertising Standards Authority, a body contracted by the Office of Communication to hear all advertising content complaints across broadcast media.19 Where complaints are made directly to the MHRA, it will investigate. If no breach of legislation or regulations is found, the MHRA may refer the complaint to an industry association to determine whether there has been a breach of a code of practice. If
a breach of the legislation or regulations is found, the MHRA has power to require an advertiser to amend or withdraw an advertisement, issue a corrective statement and/or submit future advertising for review and approval before placement. Criminal offences also apply for breaches of the Human Medicines Regulations, with the penalty being imprisonment of up to two years or a fine in most cases.

### 10.4.3.2 Complaints management benchmarking

Of the 405 complaints received in 2011-12, 373 were managed by the CRP and 67.3 per cent were found to be justified. Approximately 75 per cent of complaints related to internet advertising, and the majority of complaints related to listed complementary medicines and medical devices. Half were referred to the Secretary or the TGA. On average, the process took 135 days from receipt of the complaint to the determination date.

In 2013-14, the ASMI Complaints Panel managed two complaints that were both upheld and outcomes were published on the website. In that same period, the CHC managed 15 complaints (including four non-member complaints) and forwarded two complaints to the CRP and another four to the TGA. Timeframes for these complaints are not reported.

Performance metrics from the Australian Advertising Standards Bureau (ASB) identified that timeframes for processing of complaints could be considerably shorter if effective triaging strategies were used. In 2014, the average complaint resolution timeframe was 37.6 days, with similar results in 2013 (average 36.4 days). In urgent cases (where public health is at risk), the ASB decision can be made within 48 hours.

In the UK, complaints about a medicine can be made online to the MHRA Advertising Standards Unit, and the MHRA aims to complete an investigation within one month. The UK Advertising Standards Authority is the independent regulator of advertising across all media. It reports that for around 80 per cent of cases, it meets the target timeframes of 35 days for informal investigations, and the target of between 85 and 140 days for standard or more complex investigations.

### 10.4.3.3 Improving complaints management in Australia

The Panel came to the conclusion that the current system for managing complaints about therapeutic products in Australia should be disbanded. It is overly complex and slow, undermining its capacity to provide a disincentive for non-compliance and timely, transparent outcomes for complainants.

The Panel is of the view that a single agency should be responsible for receiving and triaging complaints, and ensuring that complaints are managed and resolved in line with best practice principles such as those set out in the Commonwealth Ombudsman’s *Better Practice Guide to Complaints Handling*.
• fairness – matters are dealt with impartially, confidentially, providing an opportunity for response and review, and with openness about the process;
• accessibility – information about processes and multiple options for lodgement are available, and barriers about making a complaint are removed;
• responsiveness – the agency is alert to and assists vulnerable clients, and unreasonable complainant behaviour is managed professionally;
• efficiency – complaints are resolved quickly, are escalated appropriately, and written complaints handling guidelines and quality assurance procedures are available;
• internal integration – complaints processes are integrated with other business activities;
• integration with other agencies – formal procedures are established for complaints referrals to other agencies to facilitate cooperation and prompt complaints management.

Complaints management processes should include prompt acknowledgement of complaints; keeping complainants informed of progress; providing a remedy where appropriate; and advising on options for the review of decisions.\(^{28}\)

The Panel considers that the agency should provide a single entry point for all complaints about therapeutic products, and triage those complaints appropriately. Complaints which centre on commercial competition between sponsors can be redirected to their industry associations or the Advertising Claims Board of the ASB.\(^ {29}\) Matters to do with adverse events or other inappropriate therapeutic outcomes, or misinformation about therapeutic uses or outcomes, should be dealt with by the NRA. Matters to do with misleading information about pricing should be directed to the ACCC.

Investigations should be prioritised in line with risks. Data arising from investigations should be analysed and contribute to post-market monitoring by the NRA and action to make systemic improvements. Regular and ad hoc reporting should be publicly available including qualitative and quantitative measures of performance, and the system should be reviewed regularly to assess its effectiveness over time.\(^ {30}\)

The Panel is of the view that, with appropriate resourcing, this function could be established within the NRA or another Commonwealth agency, or could be outsourced.
Recommendation Fifty Six

The Panel recommends that current mechanisms for managing complaints are disbanded and a new mechanism is established consistent with best practice principles for complaint handling. In establishing the new complaints management mechanism, a single agency should be responsible to receive and manage complaints on the advertising of therapeutic products to the public. The Government should consider the following options:

A. establishing the function within the NRA or other existing Commonwealth agency and ensuring appropriate resourcing for the function; or
B. calling for tenders from external organisations to undertake the function.

10.4.4 Enhancing investigative powers and penalties for breaches of the advertising framework

Across all stakeholder groups, there was a view that the current sanctions and penalties available to the NRA in respect of advertising breaches are insufficient, do not meet community expectations, and should be enhanced to incentivise greater compliance.

Where a sponsor has been found by the CRP to be non-compliant with regulatory requirements, and fails to comply within 14 days of a CRP determination, the CRP can recommend that the Secretary undertake regulatory action, including:

- suspending or cancelling the ARTG entry for the advertised goods;\(^\text{iv}\)
- order the advertiser to publish a retraction or correction;
- order the advertiser to remove advertising material or general information from the market place; and
- order that a particular claim or representation made by the advertisement be withdrawn, and not be used in any other advertisement.\(^\text{31}\)

This process, including any appeals that may be lodged, may take months to complete. During this time the advertisement generally remains in the public domain, providing financial incentives for publishers to make unsubstantiated claims for product efficacy while the compliance process is being completed.

The maximum penalty for advertising breaches is small: 60 penalty units ($10,200). Other sections\(^\text{v}\) of the Act allow for imposition of a civil penalty of up to 5,000 penalty units on an individual ($850,000) and up to 50,000 penalty units on a corporation ($8.5 million) for breaches of the Act.

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\(^{iv}\) This is only available where the sponsor was responsible for the advertisement.

\(^{v}\) For example, section 9H, *Therapeutic Goods Act 1989* (Cth).
The NRA lacks the power to impose certain sanctions and other measures, including civil penalty orders, injunctions (interim, consent and permanent), and the power to suspend/cancel an ARTG listing without notice where directions from the NRA are not complied with. In particular, there have been calls to provide the NRA with the ability to suspend advertising campaigns so that immediate action can be taken if an advertisement for a product is considered to have put public health and safety at risk.

The Panel notes stakeholders’ views that the enforcement powers and sanctions regime available to the NRA is significantly weaker than that available to the ACCC under the Competition and Consumer Act 2010\(^\text{vi}\) and available to some comparable overseas regulators. For example, in the UK the MHRA is able to commence proceedings as a criminal or civil offence, and penalty and enforcement powers provide for a fine and up to two years imprisonment for breaches of advertising requirements.\(^{32}\)

While some stakeholders questioned whether there was a demonstrated need to increase penalties and enhance powers to respond to advertising breaches, the Panel notes that there is evidence of a lack of compliance with advertising requirements. For example, in 2014, compliance breaches due to labelling and advertising of complementary medicines constituted 44 per cent of compliance breaches identified by TGA random and targeted reviews of listed medicines – the single largest category.\(^{33}\)

The Panel agrees that the current sanctions regime for breaches of the Act, Regulations and Code could be enhanced to provide the NRA with greater powers. The need to update and increase the sanctions is particularly important given the Panel’s recommendations to remove the pre-vetting process for therapeutic goods and instead implement a more self-regulatory regime (Recommendation Fifty Five refers). Without an enhancement to the NRA’s sanctions regime and powers to take action in response to advertising breaches, there is a risk that the self-regulatory scheme may lead to greater non-compliance with regulatory requirements. The Panel acknowledges that an effective deterrent regime will require that the investigation and enforcement enhancements must be complemented through increased post-market monitoring activities and compliance reviews to identify breaches (Recommendation Forty Nine refers).

Consideration as to whether the current range of investigation and enforcement powers should be broadened and enhanced could be undertaken as part of the Panel’s proposed review of the Act ( Recommendation Twenty Eight refers), and could build on the existing proposals to enhance the investigation and enforcement powers put forward in the 2013 TGA Consultation Regulation Impact Statement (RIS) on the Advertising Regulatory Framework (the 2013 Advertising RIS). However, while the 2013 Advertising RIS would be a useful starting point for consideration of changes to enforcement and investigation powers,

\(^{vi}\) For example, the ACCC can apply for permanent, consent and interim injunctions in certain circumstances: see Division 2 of Part 5-1 of the Australian Consumer Law.
if the Panel’s recommendations to no longer require pre-vetting of advertisements and for the current complaints management system to be abolished and replaced are accepted, further consultation with stakeholders and consideration of options is likely to be required.

### Recommendation Fifty Seven

The Panel recommends that, further to Recommendation Twenty Eight regarding a review of the Act, consideration be given as to whether the current range of investigation and enforcement powers should be broadened.

A comparison of the current and proposed direct-to-consumer advertising frameworks as recommended by the Panel is at Figure 17.
Figure 17: Comparison of current and proposed direct-to-consumer (DTC) advertising frameworks

**CURRENT**

- Self-listing of products by sponsors of low-risk medicines in the ARTG (AUST L) with free-text option for uses/indications
- Evidence of efficacy not freely available to consumers
- No transparency of meaning of AUST L (i.e. low awareness that their claims of efficacy are not assessed by TGA)
- Pre-approval of most (but not all) forms of DTC advertising
- No single portal for complaints from the public
- Weak enforcement powers/lack of timeliness in addressing complaints to DTC advertising
- Low number of targeted/random post-market reviews by TGA of listed medicines
- Gaming of system by certain sponsors of listed medicines which breach regulations

**PROPOSED**

- Self-listing of products by sponsors of low-risk medicines in the ARTG (AUST L) with restriction on range of uses/indications to ‘Permitted Indications’ only
- Sponsors will be required to place a summary of evidence to support any claims on approved websites
- For products listed in the ARTG through self-declaration, sponsors will be required to publish a disclaimer on product website and promotional materials that the efficacy claims for the product have not been independently assessed and/or are based on traditional use
- Abolishment of whole pre-approval process in favour of greater self-regulatory regime, with encouragement for increased NRA/industry role in compliance education
- Single portal for all complaints (NRA), with triaging of complaints
- Disband the current Complaints Resolution Panel, and have NRA, other government authority, or external agency review and manage complaints in an expeditious manner
- Increase penalties/sanctions on sponsors for breaches and non-compliance
- Increase resources for larger number of targeted/random post-market reviews
- Enable NRA to complete monitoring reviews for products withdrawn from the ARTG once sponsor is notified of an intention to review
10.5 Improving understanding and compliance of the advertising regulatory framework

The complexities of the advertising framework can make it difficult for sponsors to understand their obligations under the regulatory framework. That complexity is heightened when the party responsible for marketing and promotion of a therapeutic good is not the sponsor who obtains market approval for the product. This can contribute to non-compliance, and the associated risk of consumer protection not being met.

Proper guidance and education provides an early and cost-effective way to inform stakeholders of their obligations. At present, many industry associations offer guidance and training to member companies on their obligations under industry codes when advertising to health care professionals. The Panel also notes that until 2014 the TGACC provided training to companies who wished to advertise therapeutic goods direct-to-consumer; however this training has since been discontinued.

The Panel considers that the provision of formal sponsor education is an essential method to encourage greater compliance with the advertising framework amongst sponsors. The need for a formal education programme for sponsors will become even more acute if the Panel’s recommendation to replace the current pre-approval scheme with a more self-regulatory regime is accepted by Government, as the onus will solely be on companies to meet their obligations under the Act, Regulations and Code without a pre-vetting process. As such, the Panel recommends that the NRA facilitates the development of a formal sponsor education programme, to ensure that companies and industry associations have appropriate information and tools to assist them in achieving compliance. This programme should provide guidance on the obligations set out under the Act, Regulations and Code.

Recommendation Fifty Eight

The Panel recommends that the NRA facilitates the development of a formal sponsor education programme to provide industry and industry associations with appropriate information and tools to assist them in achieving compliance with advertising requirements under the regulatory framework.

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4 Ibid., p. 6.

vii For example, Medicines Australia’s Code of Conduct requires that any sales representative who interacts with health care professionals undertake training.
5 Ibid., p. 8.
10 Health Canada (2010, November), op. cit.
20 Ibid., p. 49.

28 Ibid., p. 31.


30 Ibid.


APPENDIX A: SUBMISSIONS RECEIVED

Arnold, Bruce Baer
Australian Self Medication Industry
Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
Australian Association of National Advertisers
Australian Medical Association
Australian Skeptics Inc
Australian Traditional-Medicine Society

Bandiera, Rhiannon

Cancer Australia
Chinese Medicine Industry Council of Australia Ltd
Complementary Medicines Australia
Consumers Health Forum

Diabetes Australia
Direct Selling Association of Australia

Federation of Chinese Medicine & Acupuncture Societies of Australia Ltd
Flordis Pty Ltd

Harvey, Dr Ken
Health Consumers of NSW

Medical Oncology Group of Australia
Musgrave, Dr Ian

NPS MedicineWise
NSW Therapeutic Advisory Group

Pfizer Australia
Pharmaceutical Society of Australia
Quality Matters Safety Matters Pty Ltd

Sanofi Consumer Healthcare

The Communications Council
The National Institute of Complementary Medicine
The Pharmacy Guild of Australia
The Royal Australasian College of Physicians
The Royal Australian and New Zealand College of Psychiatrists
The Society of Hospital Pharmacists of Australia

Wale, Dr Janet
Wesley Medical Imaging, The Wesley Hospital
APPENDIX B: CONSULTATIONS WITH STAKEHOLDERS

6 May 2015
Sanofi
Medicines and Healthcare products Regulatory Agency (UK)
Complaints Resolution Panel

15 May 2015
The National Institute of Complementary Medicine
Advisory Committee on Complementary Medicines
Complementary Medicines Australia
Australian Self Medication Industry
Macular Disease Foundation Australia

27 May 2015
Federation of Chinese Medicine & Acupuncture Societies of Australia
Chinese Medicine Industry Council of Australia
Dr Ken Harvey
Pharmacy Board of Australia
Australian Competition & Consumer Commission

11 June 2015
Advertising Standards Bureau
Australian Association of National Advertisers
The Communications Council

12 June 2015
Consumers Health Forum of Australia
Pharmaceutical Society of Australia
The Pharmacy Guild of Australia

In addition to these formal consultations, individual Panel members had some informal discussions with stakeholders and their representatives.